

Insupro Forte Capsule

For Diabetes Mellitus (type I or type II)

Clinical Trial Report

Approved by The Ministry of Health Malaysia

Background

Insupro Forte Capsules is a product for reducing sugar. It was developed by scientists of the Government of the People's Republic of China (PRC). Approval for its use in the treatment of diabetes was granted by the Ministry of Health of the PRC on 14 February 2000.

The main component of Insupro Forte Capsules is natural plant insulin. Each capsule grain contains 180 μ IU of plant insulin, detectable through serum radiation immunoassay. The insulin is heat resistant up to 59⁰C and therefore can be stored at room temperature. Other component include extracted ingredient from the balsam pear , such as balsam saponin. Insupro Forte Capsules is a first plant based insulin product. It is safe, with no known side effect.

Pharmacological and Toxicity Testing

The administration of Insupro Forte Capsules has shown significantly ($p < 0.01$) lower the blood sugar of laboratory mice after 23 days of clysters, at 1.5g/kg body weight. LD50 has not been established even at dose level of 1.5/kg body weight which is equivalent to 300 times the amount recommended for human use. Results of toxicological testing have so far been negative.

Use In Clinical Settings

Random double Blind clinical trials carried out 600 cases of diabetes in 20 hospitals in China, including:

- ✚ Accessorial Hospital of Shannxi Transitional Chinese Medicine Research Institute,
- ✚ 1st Accessorial Hospital of Xi'an Medical University,
- ✚ 323 Hospital of PLA,
- ✚ Beijing Xiyuan Hospital,
- ✚ Accessorial Hospital of Chengdu Transitional Chinese Medicine University,
- ✚ 1st Clinical Hospital of China Medical University,
- ✚ Accessorial Hospital of Dalian Medical University,
- ✚ Accessorial Hospital of Guangzhou Traditional Chinese Medical University,
- ✚ Shuguang Hospital and Longhua Hospital of Shanghai Traditional Chinese Medical University,
- ✚ Henan People's Hospital,
- ✚ Zhengzhou City Central Hospital,
- ✚ Shandong Qingdao Incretion Diabetes Research Institute,
- ✚ P Hospital of Hebei Medical University,
- ✚ Jiangsu People's Hospital,
- ✚ Accessorial Xiehe of Fuzhou Medical Institute,
- ✚ Accessorial Daping Hospital of P Military Medical University,
- ✚ Xinjiang Autonomous Region Traditional Chinese Medical University,
- ✚ Accessorial Hospital of Lanzhou 2nd Medical Institute.

The general effective ratio concluded from the study is 86.68%.

Observations have shown that Insupro Forte Capsules :

- ✚ Can control and stabilize blood sugar effectively. Fasting sugar level, post meal blood sugar levels and urine sugar are improved.
- ✚ Can control and ameliorate clinical symptoms such as thirst, hunger, and fatigue. Overall, there is improvement in diabetes control as well as quality of live.
- ✚ Can help to control triglyceride level.
- ✚ Have sustainable slow release effects, thus reducing the risk of low blood sugar.
- ✚ Can reduce the complication of diabetes, such as those related to the eye.

Insupro Forte Capsules of Clinical Effect

Insupro Forte Capsules exerts its effects through:

- ✚ Supplying exogenous insulin through the oral route.
- ✚ Activating beta cell of the pancreas so that endogenous insulin is produced.
- ✚ Improving sensitivity of the target cell to insulin.
- ✚ Bypassing the lactic acid metabolism, increasing the amount of receptors on red blood cell and enhancing insulin transport.

DOSAGE AND DIRECTION

1. DIABETES Type I

- ✚ The recommended dosage is two capsules half an hour before meal, three times a day.
- ✚ Maintain normal injection for the first 15 days. Thereafter, reduce by 4 IU every fifteen days, with monitoring of blood and urine sugar level.
(Please consult a pharmacist or doctor)
- ✚ Once the blood sugar is stabilized, patient may rely solely on Insupro Forte Capsules.

2. Diabetes Type II

- ✚ The recommended dosage is two capsules half an hour before meal, three times a day.
- ✚ Dosage can be adjust to one tablet three times a day once the blood sugar level is maintained within normal.
(Please consult a pharmacist or doctor)
- ✚ Combination with other hypoglycemic agents may be necessary in severe diabetes.
- ✚ Monitoring of blood sugar level is necessary to give an indication of dosing effectiveness.

SIDE EFFECTS AND PRECAUTION

- ✚ Overdosing of Insupro Forte Capsules will not cause hypoglycemia is a special characteristic of Insupro Forte Capsules.
- ✚ Patients on chemical hypoglycemic agents should not reduce their dose radically. A step approach with careful monitoring is advised.
- ✚ For severe cases of diabetes, the maximum dosage is three capsules three times per day.
- ✚ Dietary control should not be neglected.
- ✚ Insupro Forte Capsules is not recommended for use in pregnancy.

**A Brief Summary of Clinical Observation of Insupro Forte
Shuguang Hospital
Shanghai Traditional Chinese Medical University**

Insupro Forte Capsules is a hypoglycemic TCM preparation. Entrusted by the company, The Endocrine Section of Shuguang Hospital affiliated to Shanghai Traditional Chinese Medical University carried out a clinical observation on the curative effects of Insupro Forte Capsules in treating diabetes in December 2000. It is summarized hereunder:

General data

1. Standard for cases selection

1) Diagnostic standards

A. Western medical standard : The diagnostic standard for diabetes established by WHO in 1990:

- a) With diabetes symptoms, FPG > 7.0 mmol/L, and random PG.>11.1 mmol/L.
- b) Without diabetes symptoms, FPG > 7.0 mmol/L .Verify by a second time test.
- c) When without diabetes symptoms and FPG and Random PG under the above levels, 2hPG>11.1 mmol/L after 75g OGTT.

B. Traditional Chinese medical standard

Where such symptoms as excessive drinking, polyrexia, profuse urination, and emaciation exist.

2) Selecting standard

A. Cases to be included: DM2 cases meeting the above standard.

B. Cases to be excluded:

- a) Fewer than 18 or over 75 in age; gravid or nurturing woman; who is sensitive to the medicine.
- b) With serious heart or liver or kidney complication, or complicated with other serious primary diseases, or with mental diseases.
- c) Uncooperative (not able to abide by diet order, hence curative effects be affected).
- d) With occurrence of diabetes ketosis or ketoacidosis or infection in the latest 30 days.
- e) Not meeting the including standard; not able to follow the prescription so that curative effects cannot be properly assessed; curative effects be affected by data incompleteness.

2. Observation method

1) Case number : 30

2) Treating method: In addition to their existing treatment, patients take Insupro Forte at 2 grains/time X 3 times/day.

3) Treating course : 60 days.

3. Observation target

1) Clinical Indexes : Assess the illnesses into 4 degrees with granting points as 0 for no symptoms, 1 for light, 2 for medium, and 4 for serious.

2) Laboratory Indexes: FPG, 2hPG, and HbA1c are taken before the treatment; FPG and 2hPG taken once every 30 days; HbA1c counterchecked at the end of treatment.

4. Curative effect assessment

Standard for assessing curative effects are settled in light of Clinical Research Guide of Treating Diabetes with New Traditional Chinese Medicine.

- 1) Standard for assessing curative effects of diabetes treatment
 - A. Evidently effective: FPG<7.0mmol/L ; 2hPG<8.3mmol/L or reduced by over 30%
 - B. Effective: FPG<8.3mmol/L; 2hPG<10.0mmol/L or reduced by over 10%
 - C. Ineffective: FPG and 2hPG not meeting the above levels
- 2) Assess the curative effects on symptoms diagnosed with TCM methods.

Assess effective: Point decreased by over 2/3

 - A. Evidently effective: Points decreased by over 2/3.
 - B. Effective: Points decreases by 1/3 – 2/3.
 - C. Ineffective: Points decreased by less than 1/3.

5. **Statistical methods:** Apply Ridit Analysis to the classification data and T.test to the computation data.

- 1) General information of the patient (Table 1)

Table 1: General information of the patient: (Insupro Forte Group)

Case Number	30
Sex (M/F)	13/17
Age (Y)	58.5±8.6
Course (Y)	8.9±6.4
BMI (kg/m ²)	23.7±3.5

- 2) Curative effects on symptoms diagnosed with TCM methods (Table 2)

Table 2: Curative Effects on Symptoms Diagnosed with TCM Methods

	Case Number	E-effective Case	Effective Case (%)	Ineffective Case	General Effective Ratio case
K1s Group	30	3 (10.0)	23 (76.7)	4 (13.3)	26 (86.7)

- 3) Improvements on symptoms:(Table3,Table4)

Table 3: Improvements on Symptoms

Symptom	Before T	After T	Improved by (%)
Thirst	47	25	46.88
Hungriness	37	21	43.2
Profuse urination	43	22	48.8
Emaciation	34	25	26.5
Fatigue	59	43	27.1
Waist soreness	53	31	41.5
Skelasthenia	58	35	37.7

Table 4: Average Points of Symptoms Diagnosed with TCM Method.

Group	Before T	After T	Difference Value
Insupro Forte Group	11.4±3.9	6.7±3.3	4.6±2.2

It can be seen from Table 3 and Table 4 that after the treatment, each of the main symptoms has been evidently alleviated; the differences are significant, $p < 0.0001$.

4) Improvement on PGs: (Table5)

Table 5. Improvement on Glucose Metabolism (n=30cases)

	Before T	After T	P value
FPG (mmol/L)	6.3±2.8	7.9±2.3	0.00642
2hPG(mmol/L)	13.9±4.8	11.4±3.0	0.02702
HbA1c	8.4±2.8	7.1±1.8	0.04669

This table indicates that of the patients whose BMI ≥ 23 , either FPG or after-meal PG has been evidently reduced; HbA1c evidently reduced as well

5) Ill reaction:

No ill reaction observes during this period. Also, no patient has asked to quit in lack of patience with this medicine.

Discussion

As people living standards have been continuously improved, eruption of diabetes especially DM2 have been increasing year by year. Diabetes has become the third harmful disease of human beings after tumors and cardiovascular disease. So, it is imperative to strengthen our prevention of this disease. Our traditional medical theory takes diabetes as of “Xiaoke disease”(generally a syndrome characterized by excessive drinking and eating) category. It has been indicated by the recent studies that traditional Chinese Medicine have good effects in preventing diabetes and its chronicle complications. Insupro Forte Capsules a pure natural preparation of *momordica charatia* extracts, its efficacious composition is plant insulin. We carried out a clinical observation of this medicine. The result indicated that Insupro Forte Capsules could evidently alleviate each of the main diabetes symptoms such as thirst, hungriness, profuse urination, and fatigue. The effective ratio of treating the symptoms diagnosed with TCM methods with this capsule is up to 86.7%. Meanwhile Insupro Forte can reduced FPG and after meal PG and improve long-term glucose control of patients, as demonstrated by evident reductions in HbA1c. A further observation tells that Insupro Forte Capsules is more effective in improving glucose metabolism of the overweight and corpulent sub-group patient of whom BME ≥ 23 , this suggest that this product is possible more suitable for corpulent DM2 patients. Among the 7 cases receiving insulin treatment, glucose controlling of 3 patients were improved after taking Insupro Forte Capsules. Since we have observe a limited number of cases and been in lack of control group, our observation results need to be testified by more substantiated and rationalized clinical observation.

December 2000

Clinical Observation in 30 Cases – Treating Diabetes II with Insupro Forte Capsules

Diabetes Research Center of the 1st Clinical Medical Institute of Guangzhou Traditional Chinese Medical University

Following tumors and cardiovascular and/or cerebrovascular diseases, Diabetes mellitus has become the third harmful disease of human being. In recent year, certain progress in alleviating symptoms and preventing complication has been achieved in treating diabetes with traditional Chinese medicine. From August to November of 2000, we carried out a clinical observation in 30 cases of treating DM2 with Insupro Forte Capsules, and here is the report.

1. Data and method

1.1 Clinical data

1.1.1 General data

All the 30 cases are selected from the out and in patient specially for receiving diabetes treatment at our hospital. 13 male and 17 female; the youngest in age is 32 and the eldest is 70 with an average of 52.6; courses are 1 month for the shortest and 16 years for the longest with an average of 5.8 years. Complication of hyperlipidemia erupted in 4 cases, of hypertension in 6, of diabetic kidney disease in 2; of nervous pathology in 3, and of eye-group pathology in 1.

1.1.2 Diagnostic standard

1999 WHO standard

1.1.3 Including standards

- a) Over 20 in age;
- b) Meeting the above diagnostic standards;
- c) PG cannot be reduced to normal simply by diet control and sports treatment;
- d) PG cannot be reduced to normal by long-term taking of insulin and/or oral hypoglycemic medicines.

1.1.4 Excluding standards

- a) Over 70 in age;
- b) Gravid or nurturing woman;
- c) With occurrence of such complications as ketoacidosis, at the moment;
- d) Uncooperative
- e)

1.2 Treating method

1.2.1 Treating medicine

Insupro Forte, of which the main compositions are momordicine and *momordica charantia* saponin.

1.2.2 Treating methods

Patients of primary diabetes or of long-term diabetes but whom FPG<12mmol/L take only Insupro Forte at grains/time X 3 times/day. Patients of whom FPG>12mmol/L and who had been taking insulin and/or oral hypoglycemic medicines for long take Insupro Forte at the same dosage in addition to their treatments. After the PGs have been under control, cut down the dosages of their hypoglycemic medicine until they stop taking them at last.

1.2.3 Observation indexes

Symptoms point, FPG, 2hPG, and urine glucose quality are observed. Grade the symptoms into the degrees of Serious, Medium, Light, and Zero with 3, 2, 1, and 0 points. Mainly observe thirst, hungriness, profuse urination, emaciation, fatigue, waist soreness, and skelasthenia.

1.2.4 Standards for assessing curative effects

In light of clinical research Guide New Traditional Chinese Medicine by the Ministry of Health and with reference to the diagnostic standards by WHO in 1999, standards for assessing curative effects are resettled as the follow. Evidently effective Symptoms eliminated on the whole; FPG <6.7mmo;l/L or reduced by over 30%. Effective: Symptoms evidently alleviated FPG <7.7 mmol/L or reduces by over 10%. Ineffective: symptoms not evidently alleviated; FPG reduction not meeting the above levels.

2. Result of treatment

2.1 Curative effects of treating DM2 with Insupro Forte. Table 1.

Table 1. Curative Effects of Treating DM2 with Insupro Forte

	Cases number (n)	Curative Effects (%)
Evidently effective	10	33.3%
Effective	15	50.0%
Ineffective	5	16.7%

By analyzing this table, Insupro Forte Capsules produces comparatively good curative effects on DM2.

2.2 Comparison between clinical symptoms grading and the general points of before and after the treatment. Table 2 and Table 3.

Table 2. Comparison Between Clinical Symptoms Grading of Before and After the treatment.

	Cases Number (n)	Points (X)
Before T	30	14.76±3.78
After T	30	4.37±1.66

By self-control comparison between points of before and after the treatment, $p < 0.05$, the difference is highly significant.

Table 2. Comparison Between General Points of Before and After the treatment.

	Points		Decrease in Points (%)
	Before T	After T	
Thirst	58	11	81.0
Hungriness	40	10	75.0
Profuse Urination	50	12	76.0
Emaciation	36	16	55.6
Fatigue	53	15	71.7
Waist Soreness	42	21	50.0
Skelasthenia	44	20	54.5

It can be seen from this table that reduction in the general points are highly significant, with an average of 66.26%

2.3 Comparison between FPGs of before and after the treatment, see Table 4.

Table 4. Comparison Between FPGs of Before and After the Treatment. (X±S)

	Cases Number (n)	FPG (mmol/L)
Before T	30	12.38±2.36
After T	30	8.12±1.68

By self-control comparison between FPGs of before and after the treatment, $p < 0.05$, the difference is significant.

2.4 Comparison between 2hPGs of before and after the treatment, see Table 5.

Table 5. Comparison Between 2hPGs of Before and After the Treatment. (X±S)

	Cases Number (n)	2hPG (mmol/L)
Before T	30	14.28±4.36
After T	30	13.66±1.66

Compare by self-control comparison between 2hPGs of before and after the treatment, $p < 0.05$, the difference is significant.

2.5 Comparison between case numbers of before and after the treatment in relation with urine glucose quality, see Table 6.

Table 6. Comparison Between Case Numbers of Before and After the Treatment in Relation with Urine Glucose Quality.

	Cases Number (n)	-	+	++	+++	++++
Before T	30	16	5	6	3	4
After T	30	20	4	7	1	0

From this table it can be learned that urine glucose qualities have been evidently improved.

3. Discussion

3.1 As indicated by the result of clinical observation on the 30 cases, the general effective ration and the general improvement on symptoms point of treating DM2 with Insupro Forte Capsules are 33.3% and 83.3% respectively. From the evidently decreases in point it can be seen that Insupro Forte Capsules is effective in alleviating diabetes symptoms, $p < 0.01$, the decreases are highly significant. They are 66.2% on average symptoms such as thirst, hungriness, profuse urination, and fatigue have been most evidently alleviated.

3.2 No side and toxic effects has been found during the observation of Insupro Forte Capsules, indicating that this product is safe. The product is prepared in capsules, convenient to be taken and the dosages are comparatively small.

3.3 It can be gained from the clinical observation that Insupro Forte Capsules produces good curative effects on primary, early, light, and medium diabetes, and helps to treat the cases with long-term taking of insulin and/or oral hypoglycemic medicine as well. It works better than other pure TCM preparations in reducing FPG and after meal PG. To learn more about curative effects of Insupro Forte Capsules in treating diabetes, further and in-depth studies designed strictly in accordance with Random, Control and Blind principle of clinical research should be taken.

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During the recent year in our country, as people's living have been continuously raised, eruption of diabetes mellitus has been increasing by year. Therefore, prevention of diabetes has been listed among the national Keystone Projects. More delectable results have been achieved especially in the studies of green medicine production with pure natural plant. From March to the end of June of this year, we carried out clinical observation of Insupro Forte Capsules and the result are reported as below:

1. Clinical data

1.1 General data

Included altogether 30 cases, among which, 14 are male and 19 are female; the age are 31-81 (59 on average); illness courses are 1-18 (7.5 on average) years; for illness degree, 6 are light, 18 are medium, and 6 are serious. Simultaneous eruption of hyperlipidemia occurred in 10, of hypertension in 11, of coronary heart disease in 9, of diabetic kidney disease in 6, and of eye-ground pathology in 1.

1.2 Diagnostic and selection standards

All the 30 cases were DM2 diagnosed in accordance with provisional standards by WHO in 1980.

Cases where PG could be reduced to normal simply by diet control and increase in physical activity were excluded.

1.3 Assess symptoms with points.

Symptoms	Points			
	3	2	1	0
Thirst	Extremely	Medially	Lightly	Not
Daily drunk water	>4000	>2500	>15..	<1500
Hungriness	Still when at 1kg/day of staple food	Often when catered to with diabetic diet	Occasionally when catered to with diabetic diet	Not when catered to with diabetic diet
Profuse Urination	≥ 4000	≥ 3000	≥ 2000	>2000
Emaciation	>10kg	>5kg	<5kg	0
Fatigue	Extremely, not able to work	Evidently, difficult to work	Occasionally, able to work	Not
Waist soreness	Always	Often	Occasionally	Not
Skelasthenia	Even when sitting and lying	Often when standing or going upstairs	After labor	Not

2. Treating method

2.1 Main Composition of the medicine: momordicine, momordica charantia saponin

2.2 Treating method

Patient of whom FPG <11.2 mmol/L take only Insupro Forte Capsules at 2 grains/time X 3 times/day. Patient of whom FPG=12-20mmol/L take the same dosage of Insupro Forte Capsules in addition to the western hypoglycemic medicine they have been taking. After glucose have been under control, gradually cut down dosages of the medicine until they finally stop taking them. After glucose has been at normal for 1-2 weeks, gradually cut down the dosage of Insupro Forte Capsules to 1 grain/time X 3 times/day.

3. Observing curative effect

3.1 Standards for assessing the effects

In light of Clinical Research Guiding Principle of New Traditional Chinese Medicine by the Ministry of Health, Evidently effective: Symptoms disappeared on the whole after treatment and FPG<7.2mmol/L or reduced by over 30%; Effective: Symptoms evidently alleviated and FPG<8.3mmol/L or reduced by over 10%; Ineffective: Symptoms not evidently and FPG not meeting above levels.

3.2 Result of the treatment

Of the 30 cases, 11 are evidently effective, covering 36.37%; 15 are effective, covering 50%; and 4 are ineffective, covering 13.33%. The general effective ratio is 86.67%. Clinical symptoms especially such as thirst, hungriness, profuse urination and fatigue have been the most evidently alleviated; symptoms such as emaciation, waist soreness, and skelasthenia have more or less been alleviated as well

See Table 1-3 for comparison between clinical symptoms, FPGs, and urine glucose quality of before and after the treatment.

Table 1. Comparison Between Symptoms General Points of Before and After the Treatment.

	Points		Decrease in Points (%)
	Before T	After T	
Thirst	68	12	80.0
Hungriness	41	10	75.61
Profuse Urination	52	14	73.08
Emaciation	42	18	57.14
Fatigue	54	16	70.37
Waist Soreness	42	20	52.38
Skelasthenia	46	21	54.35

Table 2. Comparison Between FPGs of Before and After the Treatment.

	Cases Number (n)	FPG (mmol/L)
Before T	30	13.60±1.41
After T	30	8.14±1.39

P<0.05 in comparison with before the treatment

Table3. Comparison Between Cases in Relation with Urine Glucose Quality of Before and After the Treatment.

	Cases Number (n)	-	+	++	+++	++++
Before T	30	15	4	4	2	5
After T	30	20	4	6	0	0

Urine glucose quality evidently improved in comparison with of before the treatment.

4. Conclusion

4.1 Result of the observation on the 30 cases indicated that Insupro Forte Capsules can reduce elevated FPG; difference between FPGs of before and after the treatment are significant. It has evidently alleviated such clinical symptoms as thirst, hungriness, profuse urination, and fatigue and urine glucose quality as well.

4.2 This capsule work in steady and soothing way. Usually glucose can be gradually reduced to normal in 2 weeks; it is especially effective in light and medium DM2.

4.3 A halved dosage can keep reduced blood sugar still and keep it ever at normal. In a part of the cases where FPG had been reduced to 5-6mmol/, , dosage could be cut down to 1

grain/time X2 times/day before two main meals.

4.4 In case with eruption of complicated hyperlipemia, hypertension, coronary heart disease, and kidney disease, relevant treatment had been applied at the same time of taking Insupro Forte Capsules and these simultaneously erupted have been evidently alleviated.

4.5 In a case of an age female with chronic diarrhea, taking Insupro Forte Capsules once had to be stopped for it incurred eruption of her old disease. Later a combined dosage of Insupro Forte Capsules and berberine was applied and the old symptoms never occurred again. Berberine can not only improve gastrointestinal function but also help to reduce glucose.

4.6 In a case of aged male who had come from Taiwan to visit his relatives in the mainland, since the western hypoglycemic drug brought from Taiwan had been run out, he had to choose to take other medicine. But all that he had tried proved to be futile in his case. However, after he had taken this capsule, His FPG was reduced from 14.732mmol/L to 8.1mmol/L and his various symptoms evidently alleviated. This patient expressed that he would be taking Insupro Forte as a hypoglycemic medicine in all his following days.

Clinical Observation on the Treatment of Diabetes by Insupro forte Capsules
Department of Endocrinology
The 3rd Affiliated Hospital of Hebei Medical University
Wwangzhanjian Wangyan Zhaowenhui Zhizhiji Liukuanzhi Liyukun

Diabetes is a common kind of chronic endocrinal and metabolic disease. Its incidence appears to grow annually in our country. Because the etiology is still unclear, curable therapy is still not available. Most western medicines used presently have limits. So, all DM patients look forward to developing a kind of green glucose-reducing drug made from completely natural plant. Department of endocrinology in our hospital has carried out clinical observation on Insupro Forte Capsules. Here's the report:

1. Clinical Information

1.1 General Information in this study consisted of 18 male and 12 female. Their age ranged from 13 to 73 y/o, with an average age of 51.53 y/o the disease duration is from 0.5-12 years, with an average of 5.23 years.

1.2 Diagnosis Criteria and Case Selecting Standard

The 30 DM patients enroll in our study are all diagnosed in accord with the temporary diagnosis criteria of WHO (1980). Hereby the 30 cases are consisted of 4 cases type-1 DM and 26 cases of type-2 DM. Moreover, all the patients enrolled in the study are the patients whose blood glucose level seemed insensitive to single diet control therapy, exercise therapy, and/or drug therapy (including oral glucose reducing drug and insulin)

2. Therapeutic Method

2.1 The main component of the drug

Balsam pear-plant insulin P-Insulin 180 μ IU/pill

2.2 Therapeutic Method

In addition to a diet and exercise therapy, the patients took Insupro Forte Capsules by 2 pills each time for 3 times a day. If the blood glucose reduced to normal level, one would decrease the dosage of Insupro Forte Capsules to 1 pill/time, tid.

2.3 Statistic Calculation

The calculated data are express as $x \pm s$. And we adopt the method of difference test to calculate group difference.

3. Observation of Clinical Efficacy

3.1 The standard applied to assess the therapeutic effect

According to the "Guideline of Clinical Study about New Chinese Traditional Medicine" published by Ministry of Health, we define :significant effective" as "grossly appearance of Symptoms with fasting blood glucose level lower than 7.2mmol/L, or the rate is more than 30% compare with baseline FPG" ; define :effective" as great remission of symptoms with fasting blood glucose level lower than 8.3 mmol/L or the reduced rate is more than 10% compared with baseline FPG" ; and "ineffective" is defined as : no definite remission of symptoms and the blood glucose level is not reduced to the state standard".

3.2 Result

According to the data obtained from the 30 patients, there are 24 cases “significant effective”, accounting for 80%; 3 cases appear to be effective, accounting for 10%; and yet 3 “ineffective”, accounting for 10% too. So the total effective rate is as much as 90%. During the treatment, 4 cases reduced the dosage of oral glucose reducing drug, among which 2 cases reduced metformin to 25g, tid, 1 case reduced Acarbose to 50mcr, tid, and the rest 1 case reduced Gliquidone to 80mg bid; beside, 5 cases reduced their dose of insulin (3u-8u/d). We monitored the indexes of fasting blood glucose (FBG), postprandial blood glucose (PBG), blood lipid, insulin, and C-peptide before and after administration. The result indicated the drug significantly reduced F13G, P13G, triglyceride (M), and total cholesterol (TG), but enhanced high-density lipoprotein (HDL) (M.05 , M.001). This capsule showed no influence on the serum level of insulin or C-peptide (M.05).

The comparison about various indexes are listed in table 1- Table3.

Table 1 Comparison About FBG and P13G Before and After therapy.

Item	n	FBG(mmol/L)	PBG(mmol/L)
Before	30	9.81±3.14	15.99±5.12
After	30	6.44±1.36	9.7±3.47
Diference		3.37±2.7	6.32±4.41

P<0.01

Table 2 Change of Blood Lipid Level Between Pre-treatment and Post-treatment assay.

Item	n	TG	TCH	HDL
Before	30	1.79±0.99	5.56±0.98	1.05±0.28
After	30	1.50±0.63	5.200.80	1.15±0.22
Diference		0.29±0.45	0.45± 0.42	0.10±0.14

Table3 Comparison About Insulin and C-peptide before and after therapy.

Item	n	Fasting Insulin (μ IU/ml)	n	Fasting C-peptide (pmol/ml)
Before	30	16.67±7.81	28	0.85±0.49
After	30	15.10±4.91	28	0.88±0.32
Difference		0.79±5.58		0.03±24

4. Conclusion of Clinical Observation

4.1 The results of our clinical observation on the 30 patients indicate the following facts:

Insupro Forte Capsules is effectively to reduce fasting blood glucose, so the post-treatment level is significantly different from the pre-treatment level. In addition Isupro Forte Capsules also has great effect on postprandial blood glucose and blood lipid level/ It has the capability to reduced postprandial blood glucose, triglyceride, and total cholesterol, but enhance high-density lipoprotein, Thus we conclude that Insupro Forte Capsules is capable of improving not only glucose metabolism, but lipid metabolism as well.

4.2 Except for the glucose reducing effect, Insupro forte Capsules has not significant effect on insulin and C-peptide level, so its pharmacological mechanism may attribute to the enhancement of cellular sensitivity to insulin and the inversion of insulin-resistance, or may be due to promotion of synthesis of hepatic glycogen. The details of the mechanism are still under research.

4.3 The effect of Insupro Forte Capsules is stabile and modest, free from toxic and side effects. Only 1 type-1 DM patient who took insulin injection complaint mild hypoglycemia reaction and he was remitted after meal. 1 patient appeared intermittent loose stools, which may be associated with the bitterness and coldness of this drug

4.4 Insupro Forte Capsules can be used as preferred medicine or assistant medicine in treatment of DM patients.

Clinical Observation On The Therapeutic Effect Of Insupro Forte Capsules

Clinical Observation On the Therapeutic Effects of Insupro Capsules

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Insupro Forte Capsules is a traditional medicinal preparation used to control blood glucose. In this study, we observe the blood glucose (BG) reducing effect of this agent in randomized and double blind trials.

Object and Method

Objects: 45 cases of type-2 diabetes patients diagnosed by the criteria of WHO (1935), consisted of 25 male patients and 20 female patients. Average age of the patients is 52.4 years old, and the p duration of their diseases is no more than 6 years (ranged from 0.5 year to 6 year). Method: We adopt randomized and double blind method to assess the BG reducing effect of Insupro Forte Capsules. The patients are randomly divided into 2 groups, 20 in the control group, 25 in the treatment group (Table1), taking metformin for at least 2 weeks. At the beginning of the study, each volunteer was given 0.75g metformin per day (0.25g for once, 3 times a day). At the same time, patients of the treatment group took another 2 pills of Insupro Forte Capsules 3 times per day, but patient of the control group just received placebos simultaneously. When a patient's blood glucose level was higher than 11.1mmol/L, some Disha (namely, glipizide) tablets would be added into the prescription; if the blood glucose level lower than 6.1mmol/L, Disha tablets could be reduced or withdrawn. Fasting blood glucose assay and HbA1c assay are two routine examinations performed on each patient.

Statistic calculation: f test and q test are used for multi-group calculation test is a applied for two group; and X² test is utilized to treat counting data.

Results

As indicated I Table 2, in the begging of therapy, there's no significant difference between the control group and the treatment group in the aspects of glucose level, HbA1c concentration, Disha tablets taking rate (36% vs 35%) and dose ($p>0.05$). Treated for 30 days, patients of the treatment group had significantly lower blood glucose level compared with the corresponding pre-treatment concentration ($p<0.01$); but the treatment group did not get such significant reduction ($p>0.054$), and the post-treatment level was also considerable higher than that of the treatment group ($p<0.05$); HbA1c of the treatment group was somewhat reduced, but it made no significant difference ($p>0.05$).

At the 60th day, blood glucose level of the treatment group was further reduced to some extent, but it was not significantly different from the blood glucose level measured at the 300 day ($p>0.05$), neither was the taking rate or dose of Disha tablets of the treatment group ($p>0.05$). However, the HbA1c concentration appeared to be significantly lower than the baseline level ($p<0.05$); although blood glucose level of the control group was also significantly reduced at the 6e day compared with that of the 301h day ($p<0.05$), the taking rate of Disha tablets in this group increased to 85%, significantly higher than that of the

treatment group(32%, No.01), and the dose of Disha tablets was also greatly higher than both that of that the treatment group ($p<0.01$) and the baseline taken dose ($p<0.01$); beside, the HbA1c concentration of the control group at the 60th day was not significantly different from the baseline level ($p>0.05$).

Table 1. General Information of the Volunteers ($\bar{x}\pm s$)

	The control group	The treatment group
Number of cases	20	25
M/F	37934	14/11
Age (y/o)	51.5 \pm 9.7	53.2 \pm 10.7
BMI (kg/m ²)	23.9 \pm 2.7	24.01 \pm 2.2
Decease duration (years)	2.5 \pm 1.6	2.7 \pm 1.6

Table 2. Comparison of blood glucose level, HbA1c concentration, and during taking dose between the two groups and between the pre-treatment data and post-treatment data.

	The control group	The treatment group
Pre-treatment blood glucose (mmol/L)	10.27 \pm 2.28	10.54 \pm 3.46
Pre-treatment HbA1c (%)	7.33 \pm 1.54	7.22 \pm 1.69
Taken dose of Disha tablets	9.66 \pm 2.45	6.86 \pm 1.26
During therapy (mg/d)		
Blood glucose at the 30 th day (mmol/L)	7.30 \pm 1.54	Δ 7.22 \pm 1.69
HbA1c at the 30 th day (%)	7.05 \pm 1.51	6.38 \pm 1.43
Taken dose of Disha tablets At the 30 th day (mg/d)	13.23 \pm 3.03#(17)	5.56 \pm 1.58(8)*
Blood glucose level At the 60 th day (mmol/L)	7.15 \pm 0.97##	6.13 \pm 1.12
HbA1c at the 60 th day	6.47 \pm 1.30	5.98 \pm 1.08

(The numbers in the parentheses indicate the number of cases that took Disha tablets)

: $P<0.01$ data at the 36th day vs. baseline data

Δ : $P<0.05$ the treatment group vs. the control group

* : $P<0.001$ the treatment group vs. the control group

: $P<0.05$ data at the 60th day vs. data at the 30th day in the control group

** : $P<0.05$ data at the 60th day vs. baseline data in the control group

Discussion

Balsam pear has the property of clearing away heat and toxic material. It is used in Chinese traditional medicine to treat diabetes. It was in 1970s that scientist extract charantin from balsam pear, which is known as an effective glucose-reducing agent. Later, other researchers also found a glucose-reducing polypeptide in this vegetable. As indicated in pharmacological chemical analysis, this polypeptide is a basic polypeptide containing 17 kinds of amino acid. It is named as charantinin, which major pharmacological effects include: 1) act on β cell to promote secretion of insulin; 2) Compete insulin receptor with insulin to simulate the effect of insulin, therefore it is also called P-insulin(plant insulin). Charantin and charantinin are the main glucose reducing contents of Insupro Forte Capsules, so each capsules has no less than 200 μ IU P-Insulin activity.

Our study observes the glucose reducing effect of Insupro Forte by means of randomized and double blind trials. Type-2 diabetes patients, whose disease duration was no more than 6 years, took Insupro Forte (2 pills, tid) after administration of metformin for 2 weeks with no further significant decrease of blood glucose level. It is indicated that fasting blood glucose level at the 30th day of therapy was significant lower ($P < 0.01$) than baseline with an average reduction of 34.9%. While the control group took placebo in addition to metformin (0.25g, tid), and 30 days later an average reduction rate of 5.9% was observed, making no statistic difference. As some patients had fasting blood glucose level higher than 11.1mmol/L at the baseline, they were also given Disha tablets (ie. glipizide) at the same time. The taking rate of Disha tablets in the treatment group was 36%, and 35% patients in the control group also took the tablets. There was no significant difference in the data of taking rate between the two groups, nor was the data of taking dose. So we can conclude that Insupro Forte is an effective glucose-reducing drug. Further observation showed that after administration of equal dose of Insupro Forte Capsules for another 30 days, the fasting blood glucose level was further reduced but with no statistic importance. However, HbA1c, which showed no significant reduction in the first 30 days of therapy, turned to decreased significantly at the 60th day. Meanwhile, neither the taking rate nor the dosage of Disha tablets was significantly different from the corresponding baseline data. Such result suggests that Insupro Forte Capsules has the capacity to control chronic hyperglycemia and maintain stable blood glucose level. The more important points is, Insupro Forte Capsules can reduce blood glucose effectively and free from hypoglycemia reaction.

More patients in the control group took more Disha tablets from the 3 day of the therapy so that their blood glucose can be controlled to a level close to that treatment group. Because of the short therapeutic course, no significant decrease in HbA1c concentration was observed. This result indicates that Insupro Forte Capsules has similar glucose-reducing effects to Disha tablets, so it can be used to reduce blood glucose for patients with type-2 diabetes.

**Clinical observation report of the therapy for DM of Insupro Forte Capsules
The DM hospital of the QINGDAO endocrine and DM graduate school**

Balsam pear was used to treat DM in the traditional China medicine, but the effect was common. In 1970's researches separated Momordicoside with obvious anti-diabetes effects from balsam pear, in the early 1980's the Indian researches extracted an alkaline 17-amino-acid-polypeptide which was named as Charantin. Because Charantin can bind to the receptor of insulin and has an insulin like effect, it is called "plant insulin". Due to the difficulty in extraction and the high cost, it can not be used widely in clinical medicine. It is possible to produce herbal insulin on a large scale now. The main ingredients of Insupro forte Capsules are Charantin and Momordicoside with anti-diabetes effect. The activity of insulin of every capsules is no less than 200 μ IU. This research using self-matched method with historical control included 100 patients of type-II diabetes. Researchers observed the anti-diabetic effect and side-effects of Insupro Forte Capsule in this trial and the results are listed as follows:

Method and Material

1. The research's objects and the design of trail

1.1 Research objects: the diagnosis of diabetes mellitus is according to the WHO and IDF Criteria for the Diagnosis of Diabetes Mellitus in 1997: fasting plasma glucose concentration ≥ 7.0 mmol, plasma glucose 2hrs post meal ≥ 11.1 mmol. All of the subjects are chosen from the patients in the ward or the outpatient department of this hospital. Among a sum of 100, 48 are male and 52 are female. The patients' age ranged from 38 to 78 years old and the duration of their disease ranged from 1 to 15 years.

1.2. Group and design : the patients were separated into 3 group according to their fasting plasma glucose concentration.

1.2.1 Oral anti-diabetes treatment group: 7.0mmol/L $< \text{FBG} \leq 11.1$ mmol/L, a total of 30 patients (16 male, 14 female), 38-62 years old, duration of disease 1-6 year in the category of sulfonylurea, Glipizide (5mg three times per day) or Gliclazide (80 mg twice per day) was chosen, in the category of Biguanides, Glucophage was chosen (850 mg twice per day). Among the 30 patients, 15 patients took Gliclazide and Glucophage, 15 patients took Glipizide and Glucophage. After 1 month of treatment, Insupro Forte was added (2 tablets X 3 per day). The dosage of oral anti-diabetes was adjusted to maintain an ideal plasma glucose concentration. The total duration of observation was 3 months.

1.2.2 oral anti-diabetes insulin group: 11.1mmol/L $< \text{FBG} \leq 16.7$ mmol/L, a total of 40 patients (18 male, 22 female), 42-68 years old, duration of disease 5-10 years. The patients were separated into 2 subgroup according to the scheme of therapy:

A. Glucophage + insulin + Insupro forte Capsules group: 20 patients in this group. In the initial period, of Novolin50R (0.3-0.6/kg/day) were injected before breakfast and supper, Glucophage (850mg) was taken after breakfast and supper. The dosage of insulin was adjusted according to the variation of the glucose plasma glucose level. After 1 months of treatment, Insupro Forte Capsules were added (2 tablets X 3 per day). The dosage of Glucophage and insulin was adjusted to maintain an ideal plasma glucose concentration. The total duration of observation was 3 months.

B. Glipizide + Glucophage + Insulin + Insupro forte Capsules group: 20 patients in this group. In the initial period, of 6-12 units of Novolin were injected before sleep, Glipizide (5mg) was

taken before meal, Glucophage (850mg) was taken after breakfast and supper. After 1 months of treatment, Insupro Forte Capsules were added (2 tablets X 3 per day). The dosage of Glucophage, Glipizide and insulin was adjusted to maintain an ideal plasma glucose concentration. The total duration of observation was 3 months.

C. insulin treatment group (intensive treatment group) : $16.7\text{mmol/L} < \text{FBG}$, a total of 30 patients in this group (14 male, 16 females), 46-78 years old, duration of disease 8-15 years. In the initial period, of NovolinR were injected before each meal , NavolinN was injected before sleep. The dosage of insulin was 0.3-0.8/kg/day; the dosage of insulin was adjusted according to the variation of the glucose plasma glucose level. After 1 months of treatment, Insupro Forte Capsules were added (2 tablets X 3 per day). The dosage of insulin was adjusted to maintain an ideal plasma glucose concentration. The total duration of observation was 3 months.

2. method

2.1 Guideline: all the patient took OGq7 and insulin release test; their blood pressure, body weight index, renal function, blood lipid profile, HbA1c, determination for microalbuminuria in 24 hrs were also measured, then their blood pressure, body weight index, fasting plasma glucose concentration and glucose concentration 2hrs post meal, insulin level, blood lipid profile, HbA1c, determination for microalbuminuria in 24 hrs were measured monthly.

2.2 Method: glucose oxidase method for measurement of plasma glucose concentration; radio-immune assay for microalbuminuria in 24 hrs and insulin level, BPLC method for HbA1c. Renal and hepatic function, blood lipid profile were measured with an automatic biochemical analyzer.

2.3 Statistical analysis : All the result were showed in the form of $X \pm S$; T-test was used to make a historical comparison of the Insupro Forte Capsules to self control. F-test was used in the comparison among 3 groups.

Results and analysis of this trial.

1. Comparison of the clinical and biochemical characteristic among 3 groups before treatment.

As showed in table1, there was significant different among the patients of the 3 groups in age, SBP, DBP, TC, Cr, BUN, and AER. The duration of disease, level of HbA1c, FBG, PBG, TG of the patients in the insulin-treatment group were obviously higher then those of the patients in anti-diabetic group and the anti-diabetic + insulin treatment group; their BMI, FIN, PIN, were obviously lower then those of the patients in the anti-diabetic + insulin treatment group. The duration of disease, level of HbA1c, FBG, PBG, TG of the patients in the anti-diabetic + insulin-treatment group were obviously higher then those of the patients in anti-diabetic group; their BMI, FIN, PIN were lower then those of the patients in the anti-diabetic group but without significance.

Table 1. Comparison of the clinical and biochemical characteristics among three groups before treatment

	Anti-diabetic	Anti-diabetic + insulin	Insulin
Number of cases	30	40	30
Sex (M/F)	16/4	18/22	14/16
Age (year)	54.28±5.29	56.36±6.71	58.27±8.37
Duration of disease (year)	5.68±1.42	8.52±2.27*+	11.65±3.71#
BMI (kg/m ²)	26.20±2.47	24.79±2.84+	21.57±2.55*
SBP (kpa)	19.44±3.12	19.08±3.78	19.74±3.17
DBP (kPa)	11.17±2.73	10.75±2.06	11.11±3.64
HbA1c (%)	8.74±1.57	9.71±1.45*+	12.92±1.31#
FBG (mmol/L)	9.28±1.68	12.36±2.65*+	16.88±2.29#
PBG (mmol/L)	14.05±3.68	18.75±3.42*+	23.56±2.63#
FIN (μIU/ml)	12.8±4.6	8.0±3.8+	4.5±3.4*
PIN (μIU/ml)	58.6±16.7	42.8±13.6+	26.3±12.1#
TG (mmol/L)	27.9±1.45	4.86±2.82*+	6.87±3.69*
TC (mmol/L)	5.38±1.25	5.26±1.49	6.19±1.83
Cr (μmol)	69.6±41.25	72.7±48.62	75.8±46.83
BUN (mmol)	4.37±1.34	4.15±1.76	5.16±1.32
AER (mmol/L)	8.67±4.65	12.72±3.46	13.96±4.38

Note:

1. Compared with the anti-diabetic treatment group: p<0.05; #<0.01, compared with the insulin treatment group: p<0.05.
2. AER : microalbuminuria excretion rate in 24 hours; SBP: systolic blood pressure; DBP: diastolic blood pressure; FBG: fasting blood glucose; PBG: 2hrs-postmeal blood glucose. FIN: fasting insulin level; PIN: 2hrs post-meal insulin level.
3. Comparison of the clinical and biochemical characteristic among 3 groups before the treatment of Insupro Forte Capsules.

As showed in table 2, after treatment with the original scheme for 1 month. The difference of SBP, DBP, TG, TC, Cr, BUN, and AER of the patients in the 3 group was significant. HbA1c level of the patients in the insulin-treatment group was obviously higher than that of the patients in anti-diabetic group and the anti-diabetic + insulin treatment group, their FBG, PBG, BMI were lower than those of the patients in the anti-diabetic group obviously but had no significant difference from those of the patients in the anti-diabetic + insulin treatment group. HbA1c level of the patients in the anti-diabetic + insulin group, was higher that that of the patients in the anti-diabetic group, but lower that that of the patients in the insulin treatment group. Their FBG and PBG were obviously lower than those of the patients in the anti-diabetic group and had no significant difference from those of the patients in the insulin treatment group.

Table 2. Comparison of the clinical and biochemical characteristics among three groups after one month of therapy of insulin and anti-diabetic but before the treatment of Insupro

Forte Capsules

	Anti-diabetic	Anti-diabetic + insulin	Insulin
BMI (kg/m ²)	26.63±3.78	24.86±3.72	23.88±4.65*
SBP (kpa)	19.67±3.45	19.78±3.46	19.53±3.85
DBP (kPa)	11.69±3.81	10.58±2.83	11.40±3.91
HbA1c (%)	8.68±1.46	9.72±1.63#	12.37±1.58*
FBG (mmol/L)	8.18±2.58	6.65±2.35*	7.46±2.16*
PBG (mmol/L)	12.65±3.50	9.16±3.28*	8.87±2.16*
FIN (μIU/ml)	12.86±5.4	/	/
PIN (μIU/ml)	72.56±26.3	/	/
TG (mmol/L)	1.88±0.42	2.87±1.83	1.85±1.65
TC (mmol/L)	5.65±1.32	5.46±1.27	5.36±1.84
Cr (μmol)	65.8±42.13	74.6±46.76	78.6±43.88
BUN (mmol)	4.67±1.38	4.26±1.86	5.15±1.46
AER (mmol/L)	7.56±4.83	10.98±3.16	12.56±4.25

4. Comparison of the clinical and biochemical characteristic among 3 group after the treatment of Insupro Forte Capsules

(1) Oral anti-diabetic group: As showed in Table 3, in the category of Sulfonylureas, Gliclazide or Glipizide was chosen, in the category of Biguanides, Glucophage was chosen. Among the 30 patients, 15 patients took Gliclazide and Glucophage, 15 patients took Glipizide and Glucophage. After 1 month of treatment, Insupro forte were added. The dosage of oral anti-diabetic was adjusted to maintain an ideal plasma glucose concentration. After a treatment of 2 months, the PBG and HbA1c were obviously reduced; FBG had a tendency of lowering. FIN and PIN also had a trend of lowering, but without obvious variation. There was no significant variation in BMI, SW, DBP, TC CR, BUN, AER either. After a therapy of 3 months, HbA1c still showed a tendency of lowering. The other indexes had no significant difference from those after 2 months' therapy.

Table 3. The physiological and biochemical changes after the treatment of Insupro Forte Capsule of the patients in the oral anti-diabetic group

	Before the treatment of Insupro Forte Capsules	After the treatment of Insupro Forte Capsules	
		2 months	90 days after
BMI (kg/m ²)	26.63±3.78	26.25±4.17	26.87±3.66
SW (kpa)	19.67±3.45	18.72±3.41	18.63±3.76
DBP (kPa)	11.69±3.84	10.32±3.86	10.68±3.97
HbA1c (%)	8.68±1.46	7.93±1.72#	7.59±1.76#
FBG (mmol/L)	8.18±2.58	4.85±2.36	8.63±2.17
PBG (mmol/L)	12.10±3.50	9.28±3.76#	8.67±2.35#
FIN (μIU/ml)	13.86±5.4	12.63±4.8	10.18±4.5
PIN (μIU/ml)	72.56±26.3	68.87±27.8	62.68±24.7
TG (mmol/L)	1.88±0.42	1.67±0.86	1.65±0.69
TC (mmol/L)	5.65±1.32	5.76±1.38	5.32±1.26
Cr (μmol)	65.8±42.13	64.9±42.15	68.7±41.38
BUN (mmol)	4.67±1.38	4.26±1.91	4.15±1.26
AER (mmol/L)	7.56±4.83	6.97±3.12	7.53±3.23

(2) Anti-diabetic + insulin group

2. Oral anti-diabetic insulin group: a total of 40 patients in this group. The patients were separated into 2 subgroup according to the scheme of therapy:

(1) Glucophage + insulin + Insupro Forte group: In the initial period, of Novolin50R (0.3-0.6/kg/day) were injected before breakfast and supper, Glucophage (850mg) was taken after breakfast and supper. The dosage of insulin was adjusted according to the variation of the glucose plasma glucose level. After 1 months of treatment, Insupro Forte Capsules were added (2 tablets X 3 per day). The dosage of Glucophage and insulin was adjusted to maintain an ideal plasma glucose concentration. After a treatment of 2 months, FBG and PBG were higher than those before the treatment but the variation was not obvious. HbA1c level was lower than that before the treatment but without obvious variation. TG had a tendency of lowering without obvious variation. BMI, SW, DBP, BUN, CR, TC, AER had no significant variation. After 3 month's treatment, HbA1c level was obviously lower but the other indexes had no obvious variation.

Table 4. The physiological and biochemical changes after the treatment of Insupro Forte Capsule of the patients in the Glucophage + insulin + Insupro Forte group

	Before	After	
		60 days after	90 days after
BMI (kg/m ²)	26.63±3.78	25.27±4.86	25.83±3.68
SW (kpa)	19.78±3.46	18.46±3.25	18.25±3.16
DW (kPa)	10.58±2.83	11.26±3.67	10.36±3.43
HbA1c (%)	9.71±1.45	8.65±1.64	7.96±1.76
FBG (mmol/L)	6.86±2.35	9.28±3.55	8.67±2.65
TG (mmol/L)	2.87±1.83	1.95±0.88	1.98±0.55
TC (mmol/L)	5.46±1.27	5.54±1.46	5.62±1.28
Cr (μmol)	74.6±46.76	72.6±48.13	68.3±45.36
BUN (mmol)	4.67±1.86	4.67±1.93	4.65±1.28
AER (mmol/L)	10.98±3.16	12.86±3.68	10.56±3.67

(2) Glipizide + Glucophage +Insulin + Insupro forte Capsules group: 20 patients in this group. In the initial period, of 6-12 units of Novolin were injected before sleep, Glipizide (5mg) was taken before meal, Glucophage (850mg) was taken after breakfast and supper. After 1 months of treatment, Insupro Forte Capsules were added (2 tablets X 3 per day). The dosage of Glucophage, Glipizide and insulin was adjusted to maintain an ideal plasma glucose concentration. After a treatment of 2 months, FBG and M showed a tendency of lowering but the variation was no obvious. HbA1c level was obviously lower than the pre-treatment level. BMI, SW,DBP,BUN,CR,TC,AER had no significant variation. After a treatment of 3 months, HbA1c level was obviously lower. FBG and M were lower than the pre-treatment level but the variation was no obvious.

Table 5. The physiological and biochemical changes after the treatment of Insupro Forte Capsule of the patients in the Glipizide + Glucophage + insulin + Insupro Forte

group	Before		
	After		
	60 days after	90 days after	
BMI (kg/m ²)	23.78±3.65	24.57±3.73	24.88±3.42
SBP (kpa)	19.38±3.43	19.56±3.25	18.96±3.78
DBP (kPa)	10.65±2.36	11.13±2.63	10.78±3.16
HbA1c (%)	9.85±1.97	8.32±1.65*	7.94±1.66*
FBG (mmol/L)	8.65±2.35	7.46±2.38	7.58±2.41
PBG (mmol/L)	12.16±3.28	11.28±3.65*	10.67±2.65*
TG (mmol/L)	2.36±1.85	1.87±0.89	1.73±0.98
TC (mmol/L)	5.73±1.46	5.65±1.37	5.48±1.29
Cr (µmol)	82.7±48.15	76.8±42.15	78.6±46.37
BUN (mmol)	5.21±1.84	5.67±1.98	5.62±1.34
AER (mmol/L)	12.68±4.15	10.16±3.86	10.58±3.45

(3) Insulin Treatment group : As showed in table 6, after a treatment of insulin for 1 month, the FBG and PBG of the 30 patients in this group attained an acceptable level. After 1 months of treatment, Insupro Forte Capsules were added (2 tablets X 3 per day). The dosage of insulin was adjusted to maintain an ideal plasma glucose concentration. The total duration of observation was 3 months. After a treatment of 2 months, FBG and PBG showed tendency of lowering but without obvious variation. HbA1c level was higher than the pre-treatment level but the difference was no obvious. BMI, SBO, DBP, CR, TC, AER had no significant variation. After a treatment of 3 months, HbA1c level was lower and showed a tendency of descending but the difference was no obvious. The other indexes had no significant variation.

Table 6. The physiological and biochemical changes after the treatment of Insupro Forte

Capsule of the patients in the Glucophage + insulin + Insupro Forte group

	Before	After	
		60 days after	90 days after
BMI (kg/m ²)	23.58±4.65*	24.57±3.73	24.88±3.42
SBP (kpa)	19.53±3.85	19.56±3.25	18.25±3.16
DBP (kPa)	11.40±3.91	11.25±3.67	10.36±3.43
HbA1c (%)	12.37±1.58*	9.65±1.64*	8.96±1.76
FBG (mmol/L)	7.46±2.16	8.46±2.38	8.58±2.41
PBG (mmol/L)	8.87±2.16	12.28±3.65	12.67±2.65
TG (mmol/L)	1.85±1.65	1.95±0.88	1.98±0.55
TC (mmol/L)	5.36±1.84	5.54±1.46	5.62±1.28
Cr (μmol)	78.5±43.88	72.6±48.13	68.3±45.36
BUN (mmol)	5.15±1.46	4.67±1.93	4.65±1.28
AER (mmol/L)	12.56±4.25	9.87±3.32	10.51±3.19

1. The reduction of the dosage of oral anti-diabetic and insulin in the process of the therapy of Insupro Forte Capsules.

(1) oral anti-diabetic group

As showed in table 7. after taking Insupro Forte Capsules, the 30 patients reduced the dosage of anti-diabetic gradually under the precondition of maintaining an ideal FBG and PBG level. After 1 month therapy, the dosage of Glipizide was reduced by 38.9%, the dosage of Gliclazide was reduced by 44.7%. After 2 months treatment, the dosage of Glipizide was reduced by 48.9%, the dosage of Gliclazide was reduced by 56.6%. After 3 months treatment, the dosage of Glipizide was reduced by 62.1%, the dosage of Gliclazide was reduced by 64.9%.

Table 7. The circumstances of reduction of the dosage of oral anti-diabetic in the process of

the therapy of Insupro Forte Capsules

	Before	After		
		30 days after	60 days after	90 days after
Glipizide (mg/day)	15±0	9.16±3.49 (38.9%)	7.66±3.65 (48.9%)	5.68±3.72 (62.1%)
Gliclazide (mg/day)	160±0	88.36±47.44 (44.7%)	69.33±40.59 (56.6%)	56.15±42.83 (64.9%)

1. Glipizide + Glucophage + insulin group

As showed in table 8. After taking Insupro Forte Capsules, the patients reduced the dosage of anti-diabetic gradually under the precondition of maintaining an ideal FBG and PBG level. After 1 month therapy, the dosage of Glipizide was reduced by 36.6%, the dosage of Glucophage was reduced by 46.3 %. After 2 month's treatment, the dosage of Glipizide was reduced by 48.3%, the dosage of Glucophage was reduced by 67.5%. After 3 months treatment, the dosage of Glipizide was reduced by 64.4%, the dosage of Glucophage was reduced by 74.8%.

Table 8. The circumstances of reduction of the dosage of oral anti-diabetic of the patients in

the Glipizide + Glucophage + insulin group in the process of Insupro Forte Capsules

	Before	After		
		30 days after	60 days after	90 days after
Glipizide (mg/day)	15±0	9.5±1.26 (36.6%)	7.75±3.79 (18.3%)	5.34±3.28 (64.4%)
Glucophage (mg/day)	1700±0	913.75±502.39 (46.3%)	552.5±168.43 (67.5%)	56.15±42.83 (47.8%)

2. Glucophage + insulin group

As showed in table 9. After taking Insupro Forte Capsules, the 20 patients reduced the dosage of anti-diabetic and insulin gradually under the precondition of marinating an ideal FBG ang PBG level. After 1 month therapy, , the dosage of Glucophage was reduced by 46.3 %, the dosage of insulin was reduced by 14.5% After 2 moths treatment, the dosage of Glucophage was reduced by 67.5%, the dosage of insulin was reduced by 24.59%,. After 3 months treatment, the dosage of Glucophage was reduced by 74.7%, the dosage of insulin was reduced by 33.6%

Table 9. The circumstances of reduction of the dosage of oral anti-diabetic and insulin of the patients in the Glucophage + insulin group in the process of the therapy of Insupro Forte Capsules

	Before	After		
		30 days after	60 days after	90 days after
Glucophage (mg/day)	1700±0	913.75±502.39 (46.6%)	552.5±199.84 (67.5%)	428.6±168.43 (74.7%)
Insulin (U/day)	42.8±8.64	36.6±9.42 (14.5%)	32.3±12.65 (24.5%)	28.4±14.38 (23.6%)

3. Insulin Group

As showed in table 10, after taking Insupro Forte Capsules, the 30 patients reduced the

dosage of insulin gradually under the precondition of maintaining an ideal FBG and PBG level. After 1 month therapy, the dosage of insulin was reduced by 3.5%. After 2 months treatment, the dosage of insulin was reduced by 11.2%, After 3 months treatment, the dosage of insulin was reduced by 19.7%.

Table 10. The circumstances of reduction of the dosage of insulin of the patients in the insulin group in the process of the therapy of Insupro Forte Capsules

	Before the treatment of Insupro Forte	After the treatment of Insupro Forte		
		One month	Two months	Three months
Insulin (U/day)	48.2±21.76	46.5±19.73 (3.5%)	42.8±16.66 (11.2%)	38.7±18.62 (19.7%)

1. Side effect of Insupro Forte

In the process of therapy, 1 patient had severe nausea, another 1 had diarrhea. The symptoms disappeared after cessation of Insupro Forte. In the patient receiving insulin, 3 had hypoglycemia frequently after taking Insupro Forte in addition. The symptoms of hypoglycemia remitted after cessation of Insupro Forte. No renal and hepatic side-effects were found.

Conclusion

1. Insupro Forte Capsules have obvious anti-diabetic effect and are suitable for the therapy of the patients with diabetes of slight or intermediate degree.
2. The insulin level is not raised obviously after taking Insupro Forte Capsules; it is presumed that its anti-diabetic effect is related to raising the sensitivity of the receptors of insulin and the post-receptor process.
3. After taking Insupro Forte Capsules orally everyday for 6 months, the patients have no obvious injury to their renal and hepatic function.
4. Insupro Forte Capsules can replace short acting and long acting sulfonylureas partially and maintain the blood glucose concentration within an acceptable range.
5. Insupro Forte Capsules can replace Biguanides partially and maintain the blood glucose concentration within an acceptable range.
6. When used in addition to insulin, Insupro Forte Capsules can reduce the dosage of insulin obviously. Few patients had gastrointestinal side-effect in the process of taking Insupro Forte Capsules, the symptoms disappeared after cessation or reduction of Insupro Forte Capsules.

Analysis of the Result of Clinical Observation of Insupro Forte Capsules
1st Clinical Institute of China Medical University

During the period from March to August of 2000, we had been carrying out a two-month observation on curative effects of Insupro Forte Capsules on 30 cases of diabetes by making comparisons between before and after treatment and below are our report:

1. Subject: among the 30 cases diagnosed with reference to ADA, 21 are DM2 and 9 are DM1: patients' ages are 22-74 (55.47 on average) years; 19 male and 11 female; course are 1/2 – 26 (6.3 on average. Patients are divided into 3 groups depending on their BMI. BMI = 25 as normal, 2 are = 25, 21 are < 25. 16 cases are with hypertension, 15 with coronary heart disease, 2 with cerebral thrombosis, 8 with diabetic kidney disease, and 11 with retinopathy.

2. Method: randomly selects DM1 and DM2 cases and get their consent. Have them fill in the form and take their FBG, 2hPG, Insulin and C-peptide value. PG is determinates with Glucometer, insulin and C-peptide are taken with the Chemiluminescent Immunoassay System of Diagnosis Products Corporation (DPC) Tiajin Company. In the first month, apply appropriate treatment such as diet, physical activity and medicines to the patients. Then take 0 (fasting) and 120 (2 hours after meal) blood sugar as the base value before treatment; including insulin level and c-peptide value taken 1 month ago. After that, patients start to take Insupro Forte at 2 grains/time X 3times/day at 1/2 hour before meal successively for 2 months. Take again 0, 120 blood sugar at the end of the first month; 2 months later, make a countercheck in 0. 120 blood sugar, insulin level, and C-peptide.

3. Statically processing data are expressed in $X \pm S$. Apply T.test to all the parameters.

4. Result and analysis

4.1 Change in blood sugar during the 2-month treatment. Table 1: Reduction is statistically significant ($p < 0.05$)

Table 1. Change in blood sugar in before and after the Treatment (mmol/L)

	Before T	After T
FPG	9.65±2.60	7.71±1.44*
2hPG	13.01±2.84	10.75±2.72*

* $P < 0.05$ in comparison with before the treatment

4.2 Change in function of Langerhan's islet. Table 2: The result indicates no significant change in insulin and C-peptide.

Table 2. Change in Insulin Function (X±S)

	Before T		After T	
	FPins	2hpins	FPins	2hpins
Insulin (uIU)	9.25±1.41	16.85±2.67	9.16±1.40	17.74±2.71
C peptide (pmol/L)	1008.74±74.1	1803.37±490.10	1193.18±780.77	1890.83±513.64

* Compare with of before the treatment, P>0.05

4.3 Comparison between curative effects on DM 1 and DM 2. Table3 : The result indicates significant reduction (p<0.05) in blood sugar in both DM1 and DM2 cases; while no significant – is exhibited in Insulin and Cr.

Table 3. Comparison between Curative Effects on DM 1 and DM 2 (X±S)

	Before Meal		
	BG (mmol/L)	INS (u IU/ml)	CP (pmol/L)
DM 1 Before T	10.56±2.85	6.19±0.94	723.33±983.12
DM 1 After T	8.292±2.23*	5.79±0.38Δ	808.78±219.51Δ
DM 2 Before T	9.26±2.49	10.57±1.61	1131.41±307.43
DM 2 After T	7.46±2.01*	10.60±1.61Δ	1193.18±324.229Δ

	2h After Meal		
	BG (mmol/L)	INS (u IU/ml)	CP (pmol/L)
DM 1 Before T	13.78±3.72	10.98±1.64	1024.78±277.96
DM 1 After T	11.43±3.38*	11.12±1.69Δ	1097.89±297.82Δ
DM 2 Before T	12.68±3.42	19.36±2.94	2137.05±580.16
DM 2 After T	10.46±2.82*	19.72±2.99Δ	2216.46±598.73Δ

* P<0.05 for both pre-meal and after-meal BGs in DM 1 and DM 2

* P<0.05 for both pre-meal and after-meal INS and CP in DM 1 and DM 2

4.4 Compare curative effects with reference to weight indexes. Table 4 : The result indicates cannot difference in the group of BMI <25; p<0.05 for the group of =25 and >25.

Table 4. Influences of Weight Index to Curative Effects on Glucose (X±S)

BMI	Before T		After T	
	0'	120'	0'	120' (mmol/l)
<25	10.01±2.70	13.34±3.60	7.89±2.13*	10.81±2.91*
=25	9.20±2.48	12.97±3.50	7.47±2.02Δ	10.87±2.93Δ
>25	8.60±2.32	12.18±3.29	6.98±1.88Δ	10.40±2.81Δ

Δ P<0.01 Δ P<0.05

4.5 Relation between curative effects and simultaneous symptoms. Table 5: The result indicates the curative effects on the cases with capillary pathology are no so satisfactory effects on the Ones with great vessel pathology are better than those with no such symptoms.

Table 5. Simultaneous Vessel Pathology's Influences (X±S) to Curative Effects on Glucose

Pathological changes	Before T		After T	
	0'	120'	0'	120'
Capillary (4)	10.15	13.32	9.00	11.50**
Great vessel (9)	9.97	12.09	7.78	9.85*
Mixed vessel (7)	10.13	13.85	7.53	11.20*
Without vessel (19)	9.09	13.19	7.28	10.96*

* P<0.01 * P<0.05

Discussion

This research has been carried in pre-and-post control; patients take Insupro Forte Capsules in addition to receiving appropriate treatments. By analyzing the observation results, significant reductions are in either FPG or 2hPG, while no influence to insulin function is indicated. By comparing between DM 1 and DM 2 groups, improvements on both group are significant and with no evident difference in between. Checking from weight index, effects on the group of <25 seem to be best, and those on the group with simultaneous great vessel pathology and better than group with vessel pathologies.

Insupro Forte Capsules, a momordica charatia extract with biological technology. What has been found in the extract is a multiguanide substance (named P-insulin) which has insulin-like activities. The P-insulin contain in each capsule grain is not less that 180 μIU. However, this composition seems not to be monomer. So far as we observed in ten cases, it took effect not immediately but at most part in 1 month. Since these are clinical cases, we cautiously used Insupro Forte Capsule only in supplementary to the existing treatment. In

some cases, dosages of insulin and/or oral medicines were cut down after blood glucose had been under control. It can be seen that Insupro Forte Capsules had at least worked to supply insulin deficiency or eliminate insulin counteracts at certain places, if it had not directly stimulated secretion of β cell. This part of patients is still under continuing observation and we expect to see better indication of the result and to learn more about the mechanism. In all cases there has been no ill reaction.

October 20, 2000

A Summary of Clinical Observation of Insupro Forte Capsules

Authorized by Sinkiang Weiwuer Municipality Traditional Medicine Hospital has performed clinical trials on the product, Insupro Forte Capsules, in order to observe the therapeutic efficacy of this drug on Diabetic patients. The following are the results and our analysis.

1. General information

The total number of the patients is 30, including 3 MD1 and 27 DM2 patients, or 20 male patients and 10 female patients. The age of the patients range from 22 to 72 y/o, which average is 48.93 y/o. The disease duration is from 1 month to 27 years, averaging as 55.77 months. The index of body weight ranges from 19.05 to 32.03 kg/m², with an average of 24.92. The diagnosis of all patients is compliant with the diagnostics criteria of diabetes formulated by WHO in 1985. And none of the volunteers suffered from severe complication involved with the heart, the brain, the kidney, or the vessel, nor did they suffer from acute metabolic disorder at enrollment. Assessed by mean of the special traditional medical diagnostic system, those patients were also defined as obstructive manifestations due to accumulation of excessive phlegm.

2. Result of the observation

Table 1. Remission of clinical symptoms

	Number of Cases (n)			Percentage (%)			Tot Effective Rate
	Significantly Effective	Effective	Ineffective	Significant Effective Rate	Effective Rate	Ineffective Rate	
Thirsty	13	4	2	68.4	21	10.5	89.4
Starving	9	3	2	64.42	21.42	14.2	85.84
Polyuria	12	2	2	75	12.5	12.5	87.5
Leanness	3	1	2	50	17	33	67
Fatigue	14	9	2	56	36	8	92
Lumbar soreness	10	5	2	59	21	11.76	80
Limb weakness	8	3	3	57	21.5	21.5	78.5

The observation of clinical symptoms indicates that traditional medicine preparation is not only effective to reduce blood glucose, but useful to remit clinical symptoms and improve life-quality of the patients. The total effective rate concerning with the main clinical symptoms of DM patients always higher than 67%, and polyuria is the symptom most significantly remitted by the drug. Thirsty and starving just rank after the symptom of polyuria.

Table 2. Result of laboratory data

	Number of Cases (n)			Percentage (%)			
	Significantly Effective	Effective	Ineffective	Significant Effective Rate	Effective Rate	Ineffective Rate	Total Effective Rate
FPG	16	7	7	53.33	23.33	23.33	76.66
PBG	5	17	8	16.66	26.66	26.66	73.32
Urine Glucose	12	12	0	50	50	0	100

The general efficacy: According to the “ Guideline of Clinical Trial about Chinese Traditional Medicine Used to Treat Diabetes” published by ministry of Public Health, “significantly effective” is defined as :grossly disappearance of symptoms after therapy with fasting blood glucose level lower than 7.2 mmol/L and PBG lower than 8.3 mmol/L, as well as negative urine glucose”; “effective” is defined as “ much remission of symptoms with fasting blood glucose level lower than 10.0mmol/L and PBG lower than 8.3 mmol/L, as well as great reduction of urine glucose”; and “ineffective” is defined as “ no definite remission of symptoms and the reduction of blood glucose level and urine glucose is not as much as described above”. Sum up the result of FBG, PBG, urine glucose, and the clinical symptoms, there are 5 significantly effective cases, accounting for 16.66%; 17 effective cases, accounting for 56.66%; and 8 ineffective accounting for 16.66%; the total effective rate is 73.33% in all.

Conclusion

It can be concluded from the results of our observation on the 30 patients that Insupro Forte Capsules is capable of remit the symptoms of DM patients, and is also effective to reduce the level of blood and urine glucose. This drug is more beneficial for laboratory indexes than for clinical symptoms. The volunteer with shorter disease duration but in more severe status are more sensitive to the drug compare with the other patients; while patients whose disease duration are longer accompany with severe dysfunction of pancreatic island appeared either remission or aggravation in clinical symptoms.

As for the observation on the safety of this drug, we have not carried out clinical trial on this subject, because the client company has already gotten such data and put no requirement involved with this respect.

Obserce : Department of 2nd internal medicine of
Sinkiang Weiwuer Municipality TraditionalMedicine Hospital
Organizer of the observation : Likali (vice-chief doctor)
August 15th, 2000

A Summary of Clinical Observation of Insupro Forte Capsules

Wuxhangchun

Chief Member of Committee of Diabetes Speciality of Shanxi Province Academy of Chinese Traditional Medicine
Professor of Shanxi Province Institute of Chinese Traditional Medicine

Runxiaoping

Professor of Affiliated Hospital of Shanxi Province Institute of Chinese Traditional Medicine

Insupro Forte is a new product that can be used to regulate the blood glucose level of DM patient. Having no less than 200 μ IU active P-insulin, each capsule has great effect on blood glucose and is mainly used in type-1 and type-2 DM. Being a product subordinate to none toxic level, Insupro Forte is free from adverse effect. This is regarded as a big advantage of this drug, because excessive dosage will never cause hypoglycemia coma at all. Now, 20 clinical assessing trials concerning with Insupro Forte are performing in USA. Some American pharmaceutical enterprises even send mails asking for information about Insupro Forte and express their aspiration to assume the responsibility of common agency for Insupro Forte Capsules in American Market. As there is no report in the world developing another kind of single capsule containing more than 200 μ IU active P-insulin activity, Insupro Forte Capsules must have a consideration broad prospect in foreign markets.

We carried out clinical trials on Insupro Forte Capsules from January to April this year with a sum of 30 cases. 12 of these cases were significantly effective, 14 were effective, and the rest 4 cases turned to be ineffective. Thus the total effective rate accounts to 86.7%.

1. General Information

There are 14 males and 16 females. Age: 2 patients are aged from 30 to 40; 9 patients are between 41 and 50; and 19 patients are older than 51 years old. The youngest patient is 38 years old, and the oldest one is 73 years old. Most of them are elder people. Disease duration: 4 patients have been ill less than 1 year; 6 patient have a history about 1-2 years; 5 cases is 2-3 years long; 15 cases have been influenced by DM for more than 3 years. The shortest duration is just half a year; the longest one appears to be 30 years.

2. Results

1. Remission of clinical symptoms: (see table 1)

Table 1. Table of Comparison about the remission of clinical symptoms

Polyuria	Thirsty	Starving	Fatigue	Leanness	Lumbar Soreness	Limb Weakness
27	28	18	30	21	29	18
20	24	13	23	9	20	6
74.1	85.1	72.2	7.66	42.9	68.9	33.4

Note: There are evidently effective in remission of thirsty and fatigue. It is follow by polyuria, starving, and lumber soreness. While not significantly for both leanness and limb weakness.

Table 2. Clinical studies about New Chinese Traditional Medicine

Grade of efficacy	FBG	Cases (%)	2hPG	Cases (%)
Significantly effective	6	200	8	27
Effective	10	33	16	53
Ineffective	14	47	6	20
Total	30	100	30	100
Total effective rate		53		80

We can see that the total effective rate of Insupro Forte Capsules in controlling postprandial blood glucose is 80%, but the total effective rate for fasting blood glucose is just 53%. Such result suggests Insupro Forte has similar effect to insulin but it is inferior in the aspect of promoting insulin secretion.

4. Observation of indexes concerning with drug safety

1. Observation of adverse reaction: no adverse reaction was found in 30 patient who took Insupro Forte Capsules orally.
2. Observation of laboratory assay: no abnormal indexes in blood routine assay, hepatic function, and renal function examination (see the appendix assay notes) were found in the 30 patients who took Insupro Forte Capsules orally.

5. Discussion

1. Insupro Forte Capsules, a traditional medical preparation, is simply mdae from balsam pear by means of hi-tech biochemical extraction. All the patients mentioned significant improvement of symptoms like thirsty, starving, polyuria, leanness, fatigue, lumbar soreness, and limb weakness. And static calculation shows extremely significant difference ($P < 0.001$), so Insupro Forte Capsules has the capacity to regulate metabolism, reduce blood lipid, and anti-aging..
2. Regulation of blood glucose
The effective rate for fasting blood glucose is 53% ($P < 0.05$), and 80% for post blood

glucose ($P < 0.001$). So, considering from the point of regulating blood glucose, Insupro Forte Capsules has the effect similar to plant insulin. However, as the reduction rate of fasting blood glucose is not significant, we may come to a conclusion that it is relatively less effective in promoting insulin secretion.

3. The examinations of blood routine assay, hepatic function, and renal function showed no normal changes after taking the drug, therefore Insupro Forte Capsules can be regarded as non-toxic, safe, and effective.
4. Insupro Forte Capsules is especially suitable for moderate or mild DM patients.