SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

Product Name **:** PERGLIM –2 Tablets (Glimepiride 2 mg)

Strength **:** 2 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Glimepiride Tablets 2 mg

Each uncoated tablet contains:

Glimepiride USP……...2 mg

Colours: Ferric oxide (Yellow), Lake of Indigo Carmine

Excipients……q.s

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Green circular biconvex tablet, plain on both sides and blister packed.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Glimepiride is indicate as an adjunct to diet and exercise to improve the glycemic control in the adult with type 2 diabetes mellitus.

4.2 Posology and method of administration

Initially 1 mg once daily.

Titration in dose is carried out step wise as follows: 1 mg - 2 mg - 3 mg - 4 mg - 6 mg at the intervals of 1-2 weeks. Normally, a single dose is sufficient and should be taken immediately before a substantial breakfast or before the first main meal. Usual maintenance dose is 1 to 4 mg once daily. Maximum recommended dose is 8 mg once daily.

Children: Not recommended.

The route of administration is peroral.

4.3 Contraindications

Hypersensitivity to Glirnepiride or other sulphonylureas, insulin dependent (Type 1) diabetes mellitus, diabetic precoma or coma.

4.4 Special warnings and precautions for use

Keep out of reach of children.

There may be increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin.

In the initial weeks of treatment, the risk of hypoglycemia may be increased and necessitates careful monitoring. Glucose levels in blood and urine must be checked regularly, as should, additionally the proportion of glycated haemoglobin.

Use in pregnancy and lactation :

As there are no adequate and well-controlled studies in pregnant women & lactating mothers with Glimepiride, the drug should not be used during pregnancy unless clearly needed. Recent studies indicate that abnormal blood glucose levels during pregnancy may lead to congenital abnormalities.

Similarly, caution should be exercised while administrating the drug to lactating mothers. A decision whether to discontinue nursing or the drug should be taken depending on the importance of the drug to the mother.

Alertness and reactions may be impaired due to hypo-or hyper- glycemia. This may affect the ability to operate a vehicle or heavy machinery.

4.5 Interaction with other medicinal products and other forms of interaction

Hypoglycemic effect of Glirnepiride is enhanced by Anticoagulants, Androgens, Chloramphenicol, Clofibrate, Fenfluramine, Fluconazole, Histamine H2 antagonists, Magnesium salts, Methyldopa, Phenylbutazone, Probenecid, Suphonamides and Urinary acidifiers. Hypoglycemic effect Is Inhibited by the following drugs: blockers, Rifampicin, Diazoxide, Thiazide diuretics and urinary alkalisers.

4.6 Pregnancy and lactation

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Similarly, caution should be exercised while administrating the drug to lactating mothers. A decision whether to discontinue nursing or the drug should be taken depending on the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

Not available

4.8 Undesirable effects

Hypoglycemia, temporary visual impairment, gastrointestinal disturbances. Rarely thrombopenia, leucopenia, haemolytic anaemia. Occasionally allergic or pseudoallergic reactions like itching, urticaria or rashes. In isolated cases, allergic vasculitis, photosensitivity or a decrease in serum sodium may occur. Inform your doctor in case of any adverse reactions related to drug use.

4.9 Overdose

Overdosage can produce hypoglycemia. Mild symptoms without loss of consciousness can be treated with oral glucose. Severe hypoglycemic reactions like coma, seizures require medical emergencies. Hypoglycemic coma should be treated with rapid IV Infusion of conc.
Glucose (50%) solution. This should be followed by continuous Infusion of dilute glucose (10%) to maintain glucose levels above 100 mg /dL Patient should be closely monitored for 24-48 hours as hypoglycemia may recur.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics Properties:

The primary mechanism of action of Glimepiride in lowering blood glucose appears to be dependent on stimulating the release of Insulin from functioning pancreatic beta cells. In addition, extra pancreatic effects may also play a role In the activity of Glimepiride.

Glimepiride administration may lead to increased sensitivity 01 peripheral tissue to Insulin. However as with other Sulphonylureas, the mechanism by which Glimepiride lowers the blood glucose during long term administration has not been clearly established.

A mild glucose lowering effect first appeared following oral doses as low as 0.5-0.6 mg in healthy subjects. The time required to reach maximum effect was about 2-3 hours. The glucose lowering effect in all treatment groups was maintained for 24 hours.

5.2 Pharmacokinetic properties

After oral administration, Glimepiride is 100 % absorbed from the GI tract. There is significant absorption after 1 hr of administration and Cmax Is achieved within 2 to 3 hrs. When Glimepiride was given with meals, the tmax was slightly increased and AUC was slightly decreased.

After intravenous dosing in normal subjects, the volume of distribution was 8.8 L. Total body clearance was 47.8 ml/ min. Protein binding was greater than 99.5 %.

Glimepiride is completely metabolized by oxidative biotransformation after either an oral or IV dose. When radiolabelled Glimepiride was given orally, about 60 % of the total radioactivity was recovered In the urine In 7 days. About 40 % of the radioactivity was recovered in the feces. No parent drug was recovered from the urine or feces.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose, Microcrystalline cellulose, Sodium starch glycollate, Povidone, Crospovidone, Purified Talc, Magnesium stearate, Colloidal anhydrous silica.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 Months

6.4 Special precautions for storage

Keep out of reach of children

Protect from light and moisture

Store below 30°C in a dry place.

6.5 Nature and contents of container

3 blisters of 10 tablets in carton.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/HOLDER OF CERTIFICATE F PRODUCT REGISTRATION

Mega Lifesciences Nigeria Limited

6B, Guinness Road, Ogba, Ikeja, Lagos,

8. DRUG PRODUCT MANUFACTURER

Manufactured by:

Inventia Healthcare Pvt Ltd

F1-F1/1, Additional Ambernath M.I.D.C,

Ambernath (East), Thane 421506

Maharashtra State, India.

9. NAFDAC REGISTRATION NUMBER

04-8872