Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

Brand Name : **GLIBENCLAMIDE TABLETS** **Generic Name** : Glibenclamide Tablets BP 5 mg		2021
Module 1 **1.5**	Administrative Information and Product Information Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

GLIBENCLAMIDE (Glibenclamide Tablets BP 5 mg)

2. Qualitative and Quantitative Composition:

Each uncoated tablet contains: Glibenclamide BP 5 mg

3. Pharmaceutical form:

White, elongated, flat, uncoated tablets having embossed “AGOG” on one side and a breakline on the other side of each tablet.

4. Clinical particulars:

4.1 Therapeutic Indications:

Glibenclamide, also known as glyburide, is a medication used to treat diabetes mellitus type 2. It is recommended that it be taken together with diet and exercise. It may be used with other antidiabetic medication. It is not recommended for use by itself in diabetes mellitus type 1. It is taken by mouth.

4.2 Posology and Method of Administration:

Glyburide is a diabetes medicine used to help control blood sugar levels and treat type 2 diabetes.

Glyburide is available under the following different brand names: Diabeta, Glynase, and GlynasePresTab.

Dosage of Glyburide:

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Dosage Forms and Strengths

- 1.25 mg
- 2.5 mg
- 5 mg

Tablet, micronized

- 1.5 mg
- 3 mg
- 5 mg
- 6 mg

Dosing Consideraations – Should be Given as Follows:

Type 2 Diabetes Mellitus

Regular tablets

- Initial: 2.5-5 mg orally once/day
- Maintenance: 1.25-20 mg orally once/day or every 12 hours
- Not to exceed 20 mg/day
- Consider administering every 12 hours for doses greater than 10 mg/day

Micronized tablets

- Initial: 1.5-3 mg orally once/day
- Maintenance: 0.75-12 mg orally once/day
- Not to exceed 12 mg/day
- Patients at risk for hypoglycemia: 0.75 mg orally once/day initially

Transferring from insulin therapy to glyburide

- Current insulin dose less than 20 units: Discontinue insulin and initiate glyburide dose at 2.5-5 mg/day (regular) or 1.5-3 mg/day (micronized)
- Current insulin dose 20-40 units: Discontinue insulin and initiate glyburide dose at 5 mg/day (regular) or 3 mg/day (micronized)
- Current insulin dose more than 40 units: Decrease insulin dose by 50% and initiate glyburide dose at 5 mg/day (regular) or 3 mg/day (micronized); increase glyburide dose by 1.25-2.5 mg (regular) or 0.75-1.5 mg/day (micronized); decrease insulin dose gradually, based on patient's response as glyburide dose increased

Geriatric

- Initial: 1.25 mg/day if non-micronized tablets or 0.75 mg/day of micronized tablets
- Depending on glucose response, may increase dose by no more than 1.25-2.5 mg (regular) or 0.75-1.5 mg (micronized) every week

- May administer maintenance dose of 1.25-20 mg/day (regular) or 0.75-12 mg/day (micronized); for better satisfactory response may divide dose every 12 hours for patients taking greater than 10 mg/day (regular) or greater than 6 mg/day (micronized)

Dosage Modifications

- Renal impairment: If CrCl less than 50 mL/min; caution advised
- Hepatic impairment: Use conservative initial and maintenance doses; avoid use in severe liver disease
- Pediatric: Safety and efficacy not established

Dosing considerations, geriatric

- Because the elderly are susceptible to the hypoglycemic effects of glucose-lowering drugs, the question of how tightly glucose levels should be controlled is controversial
- Recognizing hypoglycemia in the elderly may be challenging
- Monitoring other parameters associated with cardiovascular disease, such as blood pressure and cholesterol, may be more important than normalized glycemic control
- Initial and maintenance dosing should be conservative
- Use caution in patients with renal insufficiency

Method of administration : Oral.

4.3 Contraindications:

- Hypersensitivity; sulfa allergy
- Type 1 diabetes
- Diabetic ketoacidosis
- Co-administration with bosentan; increased risk of hepatotoxicity

Short-Term Effects

- See "What Are Side Effects Associated with Using Glyburide?"

Long-Term Effects

- See "What Are Side Effects Associated with Using Glyburide?"

Cautions

Mifeprex

- Patients with risk of severe hypoglycemia: Elderly, debilitated, or malnourished or with adrenal or pituitary insufficiency
- Patients with stress due to infection, fever, trauma, or surgery
- Caution in hepatic or renal insufficiency

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- Caution in pregnancy/lactation
- Administration of oral hypoglycemic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin
- Hemolytic anemia may occur with glucose 6-phosphate dehydrogenase (G6PD) deficiency when treated with sulfonylurea agents
- There are no clinical studies establishing conclusive evidence of macrovascular risk reduction with anti-diabetic drugs
- All sulfonylureas are capable of producing severe hypoglycemia.

4.4 Special Warnings and Precautions for Use :

This medication contains glyburide. Do not take Diabeta, Glynase, or GlynasePresTab if you are allergic to glyburide or any ingredients contained in this drug.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.

4.5 Pregnancy and Lactation:

- Use with glyburide caution during pregnancy if benefits outweigh risks
- Animal studies show risk and human studies are not available or neither animal nor human studies were done
- It is not known if glyburide crosses into breast milk; avoid use in nursing women

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Glibenclamide, also known as **glyburide**, is a medication used to treat diabetes mellitus type 2. It is recommended that it be taken together with diet and exercise. It may be used with other antidiabetic medication. It is not recommended for use by itself in diabetes mellitus type 1. It is taken by mouth.

5.2 Pharmacokinetic Properties:

The medication works by binding to and inhibiting the ATP-sensitive potassium channels (K_{ATP}) inhibitory regulatory subunit sulfonylurea receptor 1 (SUR1) in pancreaticbeta cells. This inhibition causes cell membrane depolarization, opening voltage-dependent calcium channels. This results in an increase in intracellular calcium in the pancreatic beta cell and subsequent stimulation of insulin release.

After a cerebral ischemic insult, the blood–brain barrier is broken and glibenclamide can reach the central nervous system. Glibenclamide has been shown to bind more efficiently to the ischemic hemisphere. Moreover, under ischemic conditions SUR1, the regulatory subunit of the K_{ATP-} and the NC_{Ca-ATP}-channels, is expressed in neurons, astrocytes, oligodendrocytes, endothelial cells and by reactive microglia.

6. Pharmaceutical particulars:

6.1 List of Excipients:

Lactose	BP
Microcrystalline cellulose	BP
Maize starch	BP
Sodium Lauryl sulphate	BP
Methyl Paraben sodium	BP
Propyl paraben sodium	BP
Cross Carmellose sodium	BP
Magnesium stearate	BP
Sodium Starch Glycolate	BP
Purified talc	BP
Colloidal silicon dioxide	BP

6.2 Incompatibilities:
None Reported

6.3 Shelf-Life:
36 months from the date of manufacture.

6.4 Special Precautions for Storage:
Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:
10 tablets packed in one Blister. Such 10 blister packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

1000 tablets packed in one jar. Such jar packed in export worthy shipper.

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6.6 Special precautions for disposal:
None reported.

7. Registrant:
AGOG PHARMA LTD.
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Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

8. Manufacturer:
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9. Date of revision of the text :