

## Glibenclamide 5mg BP tablets

### 1. Name & Pharmaceutical Classification of the medicinal product

Name (and dosage form)

**Glibenclamide 5mg tablets**

Pharmacological classification

A 21.2 Oral hypoglycaemics

### 2. Qualitative and quantitative composition:

Each un-coated tablet contains:

Glibenclamide tablets BP 5mg

Excipients Q.S

### 3. Pharmaceutical Form

Off white coloured, flat surface, centrally scored on one side round shaped uncoated tablets

### 4. Clinical particulars

#### 4.1. Therapeutic indications

**Glibenclamide 5mg** is indicated as an adjunct to diet to lower the blood glucose in patients with non-insulin-dependent diabetes mellitus (type II) whose hyperglycaemia cannot be controlled by diet alone.

#### 4.2. Posology and method of administration

Route of administration: Oral

Dosage should be adapted to each individual patient and is determined by results of medical examinations.

In general the initial dose is 2, 5 mg daily (half a **Glibenclamide 5mg** tablet). The daily dose can then be raised gradually in steps of half tablets, but only after repeating medical examination. Raising the dose beyond three tablets daily does not produce any increased response.

When changing over from another oral antidiabetic preparation, with a similar mode of action, the dosage of **Glibenclamide 5mg** is determined by the amount of the previously administered dose and the medical examination. It may be considered that the effect of 1 g tolbutamide or glycodiazine, 0,5 g carbutamide or 250 mg chlorpropamide corresponds roughly to that of 5 mg **Glibenclamide 5mg** (1 tablet).

In combination therapy with a biguanide, there may be a greater risk of cardiovascular mortality than with the use of gliclazide alone.

#### 4.3. Contraindications

**Glibenclamide 5mg** is contraindicated in diabetes mellitus complicated by fever, trauma, or gangrene, and in patients with impaired renal or hepatic function or serious impairment of thyroid or adrenal function.

Diabetes mellitus in patients with a history of metabolic decompensation e.g. acidosis, diabetic pre-coma and coma.

Diabetes mellitus in young people.

Pregnancy.

#### 4.4. Special warnings and precautions for use

The administration of oral hypoglycaemic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin, although controversy exists concerning interpretation of these findings.

#### 4.5. Interaction with other medicinal products and other forms of interaction

The hypoglycaemic effects of **Glibenclamide 5mg** may be enhanced by chloramphenicol, clofibrate or halofenate, cyclophosphamide, dicoumarol, monoamine oxidase inhibitors, salicylates, phenylbutazone, propranolol and other beta-adrenergic blocking agents and sulphonamides.

The hypoglycaemic effects may be diminished by adrenaline, oestrogens, corticosteroids or diuretics. Propranolol may mask the symptoms of hypoglycaemia, and may inhibit normal physiological response to hypoglycaemia.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The dose of **Glibenclamide 5mg** may need to be reduced if you are taking the following:

- Drugs which are used to treat infections e.g. fluconazole, sulphonamides
- Pain killers e.g. aspirin, phenylbutazone
- Blood thinning agents e.g. heparin
- Cholesterol lowering agents e.g. clofibrate
- Anti-depressants e.g. MAOIs, nortriptyline
- Drugs for high blood pressure and heart failure e.g. captopril, enalapril
- Medicines for stomach ulcers and dyspepsia e.g. cimetidine, ranitidine
- Drugs for obesity and gout

The dose of **Glibenclamide 5mg** may need to be increased if you are taking the following:

- Rifampicin.
- Tablets for getting rid of water in the body.
- Drugs for high blood pressure and heart trouble.
- Some products purchased at the chemists may have a high sugar content which may raise blood sugar levels.

#### 4.6. Pregnancy and lactation

First signs of pregnancy must be reported to the doctor without delay, because a change to insulin and/or dietary treatment is necessary. Do not breastfeed whilst on **Glibenclamide 5mg** tablets without advice from your doctor.

#### 4.7. Effects on ability to drive and use machines

If you experience the symptoms of low blood sugar (hypoglycaemia) you should not drive or operate machinery. Low blood sugar may occur at the beginning of treatment while your doctor is trying to find the dose that best suits you. Your doctor will give you further advice. When your blood sugar is stabilized you may drive or operate machinery.

#### 4.8. Undesirable effects

##### Hypersensitivity reactions

Sensitivity reactions with fever, eosinophilia skin rashes, jaundice and blood disorders, including leucopenia, thrombocytopenia, aplastic anaemia, and agranulocytosis have occurred with the use of Glibenclamide.

Intolerance to alcohol, characterised by facial flushing, may also occur.

##### Gastrointestinal reactions

Glibenclamide could provoke nausea, vomiting, epigastric pain, dizziness, headache, weakness, and paraesthesia in some patients.

##### Other undesirable effects

Hypoglycaemic reactions may occur. The incidence of hypoglycaemia can be reduced if **Glibenclamide 5mg** is taken with or immediately after a meal.

When major surgery is to be performed, insulin therapy should be substituted for **Glibenclamide 5mg**.

#### 4.9. Overdose

Hypoglycaemic symptoms, e.g. excessive perspiration, light-headedness, etc. can be treated by giving the patient a glucose load.

### 5. Pharmacological properties

#### 5.1. Pharmacodynamic action

**Glibenclamide 5mg** is an oral antidiabetic preparation with a hypoglycaemic effect.

#### 5.2. Pharmacokinetic properties

**Glibenclamide 5mg** is rapidly absorbed and is extensively bound to plasma proteins, but is not readily displaced by acidic drugs. It is excreted as metabolites in urine and bile.

#### 5.3. Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

#### 5.4. Incompatibilities

Not applicable

#### 5.5. Shelf life

2 years

#### 5.6. Special precautions for storage

Do not store above 25°C

Store in original package and keep containers tightly closed

Protect from light

Keep all medicines out of reach of children

#### 5.7. Presentation

Existing pack sizes are:

3 blisters each containing 10 uncoated tablets (3 x 10 uncoated tablets)

10 uncoated tablets x 5 blisters x 2 (2 x 5 x 10 uncoated tablets)

#### 5.8. Special precautions for disposal and other handling

Not applicable

### 6. Manufacturer

Innova CapTab

81-B, EPIP, Phase -1, Jharmajri Baddi,

Distt. Solan (H.P), India.

### Importer & Distributor

Blackcedar Pharmaceuticals Ltd.

18 Owode Street, Abule-Egba,

Lagos, Nigeria

### 7. NAFDAC Registration N°: