**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S3**

**GLYCOMIN 5 mg tablets**

**Glibenclamide**

**Contains sugar: Lactose monohydrate 79,00 mg**

**Read all of this leaflet carefully before you start taking GLYCOMIN**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- GLYCOMIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**


1. What GLYCOMIN is and what it is used for
2. What you need to know before you take GLYCOMIN
3. How to take GLYCOMIN
4. Possible side effects
5. How to store GLYCOMIN
6. Contents of the pack and other information


**1. What GLYCOMIN is and what it is used for**

GLYCOMIN belongs to a group of medicines called Sulphonylureas which work by lowering the blood glucose in the body.

GLYCOMIN is used for the treatment of late onset (Type II) diabetes patients whose blood sugar is not controlled by diet alone and in whom insulin injections cannot be used.

**2. What you need to know before you take GLYCOMIN**

**Do not take GLYCOMIN:**

- if you are hypersensitive (allergic) to glibenclamide or other sulphonylurea medicines or to any of the other ingredients of GLYCOMIN (listed in section 6).
- If you have insulin dependent (Type I) diabetes.
- If you are younger than 18 years old.
- If you are suffering from ketoacidosis (caused by very high levels of blood sugars in diabetics).

- If you are suffering from a severe infection or stress.
- If you have severe liver disease, including that caused by a weak heart or alcoholism
- If you have severe kidney or thyroid disease.
- If you suffer from reduced function of the adrenal gland. (This gland causes the production of hormones that affect starch and salt usage in the body, sexual development of the body and controls the body's response to stress).
- If you have reduced consciousness or coma resulting from your diabetes.
- If you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

**Warnings and precautions**

Take special care with GLYCOMIN:

- If you have kidney disease, as a reduced dose may be required.
- As its use has been connected to more deaths as a result of heart disease when compared to the use of diet changes and diet changes plus insulin use alone.
- If you are suffering from repeated infections or shock.
- Before undergoing major surgery as your GLYCOMIN will need to be substituted for insulin
- After you have been under anaesthesia.
- As it may result in an intolerance to alcohol, which is characterized by redness or sensitivity of your face.
- As low blood sugar reactions, like sweating, hunger, heart palpitations, weakness/ light headedness, fits, confusion, may occur.

**Children and adolescents**

Do not give this medicine to children as safety has not yet been established.

**Other medicines and GLYCOMIN**

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Tablets containing the active ingredient Metformin as using it together with GLYCOMIN could lead to heart problems.
- Medicines containing any of the following as they may cause a further lowering of the blood sugar and may need your doctor to lower the dose of GLYCOMIN:
  - Antibiotic medicines like chloramphenicol or tetracycline.

- Anti-blood clotting medicines of the coumarin class (like warfarin or dicumarol). Note that GLYCOMIN may, also increase the effects of these anti-blood clotting medicines.
- Anti-inflammatory medicines (like aspirin and ibuprofen).
- Cholesterol lowering medicines (like clofibrate and halofenate).
- Stomach acid reducing medicines (like cimetidine and ranitidine).
- Blood pressure lowering medicines in the ACE inhibitor category (like captopril and perindopril).
- Antifungal medicines of the azole category (like miconazole and clotrimazole).
- Antidepressant medicines of the tricyclic category (like imipramine and amitriptyline).
- Antidepressants medicines of the monoamine oxidase inhibitor category (like selegiline and moclobemide).
- Fenfluramine, indobufen, methyldopa, miconazole, sulphinpyrazone, allopurinol, cyclophosphamide, dicoumarol, heparin, octreotide, quinidine and quinine.

- Medicines containing any of the following as they tend to hinder the action of GLYCOMIN and may need your doctor to increase the dose:
- Aminoglutethimide, asparaginase chlorpromazine, diazoxide, epinephrine (adrenaline), rifampicin, and thyroid hormones.
- Medicines in the corticosteroid category (like prednisone and cortisone).
- Oral contraceptives.
- Medicines of the beta-blocker category (like atenolol and propranolol).
- Medicines that helps the body get rid of excess salt and water that are from the thiazide category (like hydrochlorothiazide and Indapamide).

**GLYCOMIN with food, drink and alcohol**

- Alcohol: GLYCOMIN may interact with alcohol usage and cause additional drop in blood glucose as well as intolerance to alcohol characterised by redness in the face.
- The further lowering of the blood sugar caused by the medicines mentioned above can be reduced if GLYCOMIN is taken with or immediately after a meal.

**Pregnancy, breastfeeding and fertility**

You should not take GLYCOMIN if you are pregnant or breastfeeding your baby.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

**Driving and using machines**

Until blood glucose control is achieved, or when changing from one medicine to another, or when tablets are not taken routinely, your alertness and capacity to react may be impaired to such an extent that you may not be fit to drive, or to operate machinery (see section 4).
It is not always possible to predict to what extent GLYCOMIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GLYCOMIN affects them (see section 4).

**GLYCOMIN contains Lactose monohydrate**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take GLYCOMIN**

Do not share medicines prescribed for you with any other person.
Always take GLYCOMIN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The usual starting dose of GLYCOMIN is 2,5 mg orally daily with or immediately before breakfast. Your doctor may adjust it after about 7 days up to a maximum of 15 mg (Three /3) GLYCOMIN tablets.
If your dose is in the maximum range, your doctor may instruct you to take part of the dose later in the day.
Your doctor will tell you how long your treatment with GLYCOMIN will last. Do not stop treatment early. If you have the impression that the effect of GLYCOMIN is too strong or too weak, tell your doctor or pharmacist.

**If you take more GLYCOMIN than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Signs and symptoms of overdosage may be those that are due to extremely low blood sugar such as e.g. excessive perspiration, light-headedness, etc. If untreated, these may lead to fits, coma and/ or death.

**If you forget to take GLYCOMIN**

Do not take a double dose to make up for forgotten individual doses.

**If you stop taking GLYCOMIN**

Do not stop taking GLYCOMIN without speaking to your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

GLYCOMIN can have side effects.

Not all side effects reported for GLYCOMIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GLYCOMIN, please consult your healthcare provider for advice.

If any of the following happen, stop taking GLYCOMIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Nosebleeds, bleeding gums, blood in urine, bruising and/or purple spots on the skin.
- Fatigue, dizziness, heart palpitations, pale skin, headache, confusion.
- Having recurring infections.
- Yellowish skin and eyes, pain in the upper right part of the stomach.

These reactions are the result of possible blood or liver disorders that are potentially life threatening.

The following are very serious side effects. Though they are often temporary and disappear with continued use of GLYCOMIN, tell your doctor immediately or go to the casualty department at your nearest hospital if they continue:

- Skin reactions characterised by itchy raised bumps that turns white when pressed (urticaria) followed by difficulty in breathing and dizziness/weakness and confusion.
- Skin reactions characterised by tender, purple or brownish-red spots, sores or blisters that are spread over large areas of the body, mainly the legs buttocks and chest (vasculitis).
- The following side effects are frequently encountered, but tends to go away once your dose is reduced:
- Constipation, diarrhoea, gassiness, heartburn, loss of or increase in appetite, nausea, stomach feeling full, vomiting, pain in the area just below the ribs.

Tell your doctor if you notice any of the above so that they can review dosage for possible reduction.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- Tiredness, paleness, shakiness, sweating, hunger, confusion blurred vision – these are all symptoms of low blood sugar and may also occur at night.
- Weight gain.

- Frequent urination.
- Changes in sensation of taste, dizziness, drowsiness, headache, weakness.
- Burning, prickling or numbness sensation in the hands, arms, legs, feet or other parts of the body.

*Less frequent side effects*

- Pale skin, cold hands and feet, dizziness, proneness to infections and shortness of breath, swollen lymph nodes, blisters inside the mouth and unusual bleeding. These occur due to one or more of the blood components not forming or performing normally and is part of a range of diseases called anaemias and blood dyscrasias.
- Severe low blood sugar that leads to seizures and coma.
- Dark coloured urine, light coloured stool, yellowish skin or eyes and itchiness, weight loss, bone pain, increased bruising which are all due to liver disorders.
- Severe stomach, chest, leg or back pain, anxiety, confusion, hallucinations, painful, blistering skin lesions that develop on sun-exposed skin (photosensitivity) that occur due to a build-up of the natural chemicals that are required to make the red blood cells that carry oxygen around your body (indicative of a condition called porphyria).
- Formation of bulging, red, pink, purple, or brown rash-like lesions that are usually circular that may have a blister at the centre and is similar in appearance to a bullseye (the condition is called erythema multiforme).
- Redness and peeling of the skin over large areas of the body (the condition is called exfoliative dermatitis).

*Side effects with an unknown frequency*

- Low blood levels of salt which can cause tiredness and confusion, muscle twitching, fits and coma (hyponatraemia).
- Confusion, hallucinations, and jumbled speech after a short period of anxiety (psychosis), (encephalopathy).
- Body shaking/ tremors.
- Weakness/ numbness of one side of the face or body, or inability to produce or understand speech, vision changes, and balance difficulties due to problems in the blood vessels of the brain.
- Visual disturbances like blindness, double vision – commonly occurs at the start of treatment.
- Deafness or ringing in the ears.

- Pain in the abdominal area that radiates to the back and tends to get worse after eating and is accompanied by nausea, vomiting and fever (pancreatitis).
- Allergic skin reactions that don't get better over time.
- Hair loss.
- Tender, red bumps, usually found symmetrically on the front part of the leg below the knee that are accompanied by fever and joint pain (erythema nodusum).
- Itchiness.
- Swelling of the face.
- Joint pain.
- Water retention and low sodium levels that lead to lethargy and confusion, cramps, muscle twitching (Syndrome of inappropriate secretion of antidiuretic hormone (SIADH).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Reporting can also be done directly to Adcock Ingram Limited at:

**E-mail:** Adcock.aereports@adcock.com

**Tel:** 011 635 0134

By reporting side effects, you can help provide more information on the safety of GLYCOMIN.

**5. How to store GLYCOMIN**

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in a dry place and protect from light.

Keep in the original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

**6. Contents of the pack and other information**

**What GLYCOMIN contains**

GLYCOMIN: The active substance is glibenclamide 5 mg.
The other ingredients are colloidal silicon dioxide, lactose monohydrate, magnesium stearate, purified talc, starch maize.
Contains sugar: Lactose monohydrate 79,00 mg

**What GLYCOMIN looks like and contents of the pack**
GLYCOMIN is white, flat, oblong, bevelled edge tablet, bisected on both sides.

30 or 500 tablets are packed in a white polypropylene or HDPE container sealed with a white LDPE or polypropylene cap, together with a white foam or rayon insert, and a leaflet.

100 tablets are packed in a white polypropylene or HDPE container sealed with a red LDPE or polypropylene cap, together with a white foam or rayon insert, and a leaflet.

Patient ready packs:
28, 56 or 84 tablets are packed into metallised layflat bags (metallised polyester laminated to opaque linear low density polyethylene), with a low density polyethylene ziploc.

28, 56 or 84 tablets are packed into metallocene layflat bags (polyester laminated to aluminium foil and clear metallocene material), with a low density polyethylene ziploc.

The patient ready packs are grouped, packed and sealed into polyethylene bags together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

**Holder of Certificate of Registration**
Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand, 1685
Customer Care: 0860 ADCOCK/ 232625

**This leaflet was last revised in**
26 April 2022

**DATE OF APPROVAL: 26 APRIL 2022**

**PATIENT INFORMATION LEAFLET**

**Registration number**

Q/21.2/24

adcock ingram

31044 10/2022
31446 10/2022
310448 10/2022

**DATE OF APPROVAL: 26 APRIL 2022**