

GLIBETA TABLETS (5mg + 500mg)

Glibenclamide and Metformin Hydrochloride (5mg + 500mg)

What is in this leaflet

1. What is GLIBETA used for
2. How GLIBETA works
3. Before you use GLIBETA
4. How to use GLIBETA
5. While you are using it
6. Side effects
7. Storage and Disposal of GLIBETA
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What GLIBETA is used for

Your doctor has prescribed GLIBETA to treat your type 2 diabetes. This is also known as non-insulin-dependent diabetes mellitus.

How GLIBETA works

GLIBETA combines 2 glucose lowering drugs, glibenclamide and metformin.

These 2 drugs work together to improve the different metabolic defects found in type 2 diabetes. Glibenclamide lowers blood sugar primarily by causing more of the body's own insulin to be released, and metformin lowers blood sugar, in part, by helping your body use your own insulin more effectively.

Together, they are efficient in helping you to achieve better glucose control.

Before you use GLIBETA

- When you must not use it

Do not take GLIBETA if you:

- Are allergic (hypersensitive) to glibenclamide, metformin or other sulphonylureas or any of the other ingredients in Tablets.
- Suffer from early onset or type 1 diabetes (requiring insulin).
- Suffer from severe kidney disease.
- Suffer from liver problems.
- Are suffering from any condition likely to make controlling your blood sugar difficult.
- Are due to undergo surgery.
- Are pregnant.
- Have reduced consciousness or coma resulting from your diabetes.
- Are elderly (over 70 years of age).
- Have reduced kidney function.
- Have lactic acidosis [too much lactic acid in the blood (see "Risk

of lactic acidosis" below)] or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe).

Pregnancy and lactation

During pregnancy, you need insulin to treat your diabetes. Tell your doctor if you are, you think you might be or are planning to become pregnant, so that he or she may change your treatment.

Do not take this medicine if you are breast-feeding or if you are planning to breast-feed your baby.

- Before you start use it

You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels. This means, apart from regular tablet intake, you observe the dietary regimen, have physical exercise and, where necessary, reduce weight.

During GLIBETA treatment regular monitoring of your blood (and possibly urine) sugar level and also your glycated haemoglobin (HbA1c) is necessary.

In the first few weeks of treatment, the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. So particularly close medical monitoring is necessary.

Low blood sugar (Hypoglycaemia) may occur:

- If you take meals irregularly or skip meals altogether.
- If you are fasting.
- If you are malnourished.
- If you change your diet.
- If you increase your physical activity and carbohydrate intake does not match this increase.
- If you drink alcohol, especially in combination with skipped meals.
- If you take other medicines or natural remedies at the same time,
- If you take too high doses of glibenclamide or metformin.
- If you suffer from particular hormone-induced disorders

(functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex).

- If your kidney function or liver function is severely decreased.

If you have low blood sugar you may have the following symptoms: headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness, and helplessness.

The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heartbeat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self-control, your breathing may be shallow and your heartbeat slowed down, you may become unconscious.

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, e.g. glucose tablets, sugar cubes, sweet juice, sweetened tea.

You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Remember that artificial sweeteners are not effective. Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

Symptoms of low blood sugar may be absent, less obvious or develop very slowly or you are not aware in time that your blood sugar level has dropped.

This may happen if you are an elderly patient taking certain medicines (e.g. those acting on the central nervous system and beta-blockers).

If you are in stress-situations (e.g. accidents, surgical operations, fever etc.) your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar (hyperglycaemia) may occur when

GLIBETA TABLETS (5mg + 500mg)

Glibenclamide and Metformin Hydrochloride (5mg + 500mg)

GLIBETA has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor or in special stress situations). These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance. If these symptoms occur, you must contact your doctor or pharmacist.

If you have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anaemia) can occur. Contact your doctor before taking this medicinal product.

GLIBETA is not recommended for use in children due to a lack of data.

GLIBETA use is associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin. Before taking GLIBETA consult your doctor for potential risks and advantages of GLIBETA tablets and of alternative models of therapy.

Treatment with GLIBETA may rarely cause a serious condition called lactic acidosis (where there is too much acid in the blood) which requires urgent hospital treatment to prevent it leading to coma. Other illnesses, prolonged fasting, poor blood sugar control, or alcohol intake can all increase the risk of lactic acidosis developing. You should be aware of the warning symptoms which include muscle cramps, abdominal pain, breathlessness and a feeling of being very weak and unwell. If you develop these symptoms you must tell your doctor immediately. Your doctor should check that your kidneys are working properly at least once a year or more often if needed.

GLIBETA therapy should be temporarily suspended for any surgical procedure (except minor procedures not associated with restricted intake of food and fluids) and should not be restarted until the oral intake has resumed and renal function has been evaluated as normal.

Certain individuals (those with inadequate vitamin B12 or calcium

intake or absorption) appear to be predisposed to developing subnormal vitamin B12 levels. In such cases, routine serum vitamin B12 measurements at 2- to 3-year intervals may be useful.

Risk of lactic acidosis

Metta SR may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease). If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Metta SR for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Metta SR and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- Vomiting.
- Stomach ache (abdominal pain).
- Muscle cramps.
- A general feeling of not being well with severe tiredness.
- Difficulty in breathing.

Lactic acidosis is a medical emergency and must be treated in a hospital.

During treatment with Metta SR, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

- Taking other medicines

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

prescription, as they may interact with your GLIBETA.

The blood sugar lowering effect of GLIBETA may be strengthened and signs of low blood sugar levels may occur when one of the following medicines is taken:

- Other medicines used to treat high blood sugar (oral antidiabetics or insulin).
- Antibiotics (e.g. Sulphonamides, chloramphenicol, ciprofloxacin).
- Medicines to treat high blood pressure or heart failure (beta blockers).
- Medicines to treat fungal infections (miconazole).
- Medicines to treat depression (monoamine oxidase inhibitors).
- Painkiller or antirheumatics (salicylates).
- Medicines containing alcohol.

The blood glucose lowering effect of GLIBETA may be weakened and raised blood sugar levels may occur when one of the following medicines is taken:

- Thiazides and other diuretics (water pill).
- Corticosteroids.
- Phenothiazines.
- Thyroid products.
- Estrogens.
- Oral contraceptives.
- Phenytoin (drug used to treat epilepsy).
- Nicotinic acid.
- Sympathomimetic.
- Calcium channel blocking drugs (drug used to treat high blood pressure).
- Isoniazid (drug used to treat tuberculosis).

Consult your doctor before you start taking another medicinal product. If you go into hospital, tell the medical staff you are taking GLIBETA.

How to use GLIBETA

- How much to use

Adults

The usual starting dose is one tablet twice daily with meals. Doctor will tell you the exact dose for you to take. After 10 to 15 days, your doctor may slowly increase your dose until the right dose for you is reached. This will help lower the chances of getting side effects

GLIBETA TABLETS (5mg + 500mg)

Glibenclamide and Metformin Hydrochloride (5mg + 500mg)

such as feeling sick (nausea) or being sick (vomiting).

The maximum recommended daily dose of 2000 mg metformin/20 mg glibenclamide is given.

For patients not adequately controlled on either glibenclamide (or another sulphonylurea) or metformin alone, the recommended starting dose of Fixed Dose Combination (FDC) for Metformin and Glibenclamide is 500/2.5 mg or 500/5 mg twice daily with the morning and evening meals.

However, Fixed Dose Combination for Metformin and Glibenclamide 500mg/2.5 mg is not available for GLIBETA.

- When to use it

- Taken with or immediately after breakfast or your first main meal. This lowers the chance of getting an upset stomach.
- Swallow the tablets whole with a glass of water.
- Do not crush or chew the tablets.
- Try to take your medicine at the same time each day so that it becomes part of your daily routine.

- How long to use it

Keep taking GLIBETA until your doctor tells you to stop. Do not stop taking GLIBETA just because you feel better. If you stop your illness may get worse.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember, with your next meal. However, if it is time for your next dose, do not take the missed dose. Take only a single dose as usual.

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

- If you use too much (overdose)

Signs that could indicate you have taken too many are symptoms of low blood sugar which include sweating, hunger, increased heart rate, reduced consciousness, coma or seizures.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much

of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Tell your doctor if you develop symptoms such as feeling very weak, tired or uncomfortable; unusual muscle pain; trouble breathing; unusual or unexpected stomach discomfort; feeling cold; feeling dizzy or lightheaded; or suddenly developing a slow or irregular heartbeat.

If you notice these symptoms, or if your medical condition has suddenly changed, stop taking GLIBETA tablets and call your doctor right away. Lactic acidosis is a medical emergency that must be treated in a hospital.

Tell your doctor if you have an illness that results in severe vomiting, diarrhea, and/or fever or if your intake of fluids is significantly reduced. These situations can lead to severe dehydration, and it may be necessary to stop taking GLIBETA temporarily.

You should let your doctor know if you are going to have any surgery or specialized x-ray procedures that require injection of contrast agents. GLIBETA therapy will need to be stopped temporarily in such instances.

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists that are treating you that you are taking GLIBETA.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give GLIBETA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of Driving and using machines

If your blood sugar is not well controlled then this can affect your vision and/or concentration. If you are affected in any way do not drive or operate machinery.

Side effects

Like all medicines, GLIBETA can cause side effects, although not everybody gets them.

The most commonly observed side effect is low blood sugar (hypoglycaemia). Symptoms and signs are already discussed in “Before you start to take it”. If left untreated these symptoms could progress to drowsiness, loss of consciousness or possibly coma. If an episode of low blood sugar is severe or prolonged, even if it is temporarily controlled by eating sugar, you should seek immediate medical attention.

Other side effects include:

Metabolism and nutrition disorders:

- Decrease of vitamin B12 absorption with decrease of serum levels during long-term use of GLIBETA.
- Lactic acidosis.

Gastrointestinal disorders:

Diarrhea, vomiting and abdominal pain with FDC Metformin and Glibenclamide and more frequent at higher dose. Skin become yellow (cholestatic jaundice) and hepatitis may occur that may lead to liver failure. FDC Metformin and Glibenclamide must be discontinued if this occurs.

Liver disorders:

Liver function tests abnormalities or hepatitis resolving upon GLIBETA discontinuation.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website nprra.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Epimate

- Storage

- Store below 30°C.

GLIBETA TABLETS (5mg + 500mg)

Glibenclamide and Metformin Hydrochloride (5mg + 500mg)

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Yellow coloured capsule shaped biconvex film coated tablets debossed with “5” on one side and plain on the other side.

- Ingredients

Active ingredients:

- Metformin Hydrochloride.
- Glibenclamide.

Inactive ingredients:

- Microcrystalline cellulose.
- Croscarmellose Sodium.
- Polyvinyl Pyrolidone.
- Magnesium stearate.
- Hydroxy Propyl Methyl Cellulose.
- Hypromellose.
- Purified Water.
- Polyethylene Glycol 6000.
- Talc.
- Titanium Dioxide.
- Ferric oxide yellow.

- MAL number:

MAL15125033AZ

Manufacturer

Torrent Pharmaceuticals Limited
Indrad 382 721, Tal: Kadi,
City: Indrad, Dist. Mehsana,
India

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn.
Bhd.
Suite E-08-08 Plaza Mont Kiara,
No. 2 Jalan Kiara Mont Kiara,
50480 Kuala Lumpur,
Malaysia.

Date of revision

26/06/2019

Serial Number

NPRA(R2/1)190626/179