

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

METFORMIN 500 BIOTECH, 500 mg, film-coated tablet

METFORMIN 850 BIOTECH, 850 mg, film-coated tablet

Metformin hydrochloride

Contains sugar (lactose monohydrate).

METFORMIN 500 BIOTECH contains 10,8 mg and

METFORMIN 850 BIOTECH contains 14,4 mg per film-coated tablet.

Read all of this leaflet carefully before you start taking METFORMIN BIOTECH

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

1. What METFORMIN BIOTECH is and what it is used for

METFORMIN BIOTECH contains metformin, a medicine to treat diabetes. It belongs to a group of medicines called biguanides.

If you have diabetes, your pancreas does not make enough insulin or your body is not able to use properly the insulin it produces. This leads to a high level of glucose in your blood. METFORMIN BIOTECH helps to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking METFORMIN BIOTECH over a long period of time also helps to lower the risk of complications associated with diabetes. METFORMIN BIOTECH is associated with either a stable body weight or modest weight loss.

METFORMIN BIOTECH is used to treat patients with type 2 diabetes (also called 'non-insulin dependent diabetes') when diet and exercise alone have not been enough to control your blood glucose levels. It is used particularly in overweight patients.

Adults and children over 12 years of age can take METFORMIN BIOTECH on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).

2. What you need to know before you take METFORMIN BIOTECH

Do not take METFORMIN BIOTECH:

- if you are hypersensitive (allergic) to metformin or any of the other ingredients of METFORMIN BIOTECH (listed in section 6).
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (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 include stomach pain, fast and deep

breathing, sleepiness or your breath developing an unusual fruity smell.

- if you have severely reduced kidney function.
- if you lost too much water from your body (dehydration), such as due to long-lasting or severe diarrhoea, or if you have vomited several times in a row. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see Warnings and precautions).
- if you have a severe infection, such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see Warnings and precautions).
- if you need to have an examination such as X-ray or scan involving the injection of contrast medicines that contain iodine into your bloodstream.
- if you are treated for acute heart failure or have recently had a heart attack, have severe problems with your circulation (such as shock) or have breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see Warnings and precautions).
- if you have liver problems.
- if you drink a lot of alcohol.
- if you are pregnant or breastfeeding your infant.

Warnings and precautions

Take special care with METFORMIN BIOTECH:

Risk of lactic acidosis

METFORMIN BIOTECH 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 (see further information below), 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).

Stop taking METFORMIN BIOTECH 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 METFORMIN BIOTECH 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
- reduced body temperature and heartbeat

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

During treatment with METFORMIN BIOTECH, 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.

If you need to have major surgery, you must stop taking METFORMIN BIOTECH during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with METFORMIN BIOTECH.

You should continue your diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.

The usual laboratory tests for diabetes monitoring should be performed regularly.

Tell your doctor if you suffer from a blood disease that is caused by a deficiency of vitamin B12 and folic acid.

METFORMIN BIOTECH on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take METFORMIN BIOTECH together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides), there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, vision disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

Children and adolescents

Do not use in children younger than 12 years of age.

Other medicines and METFORMIN BIOTECH

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

- iodinated contrast medicines.
- medicines which increase urine production (diuretics).
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- corticosteroids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma).

- medicines that may change the amount of METFORMIN BIOTECH in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).
- medicines used to treat clotting (anticoagulants).
- other medicines used to treat diabetes.

METFORMIN BIOTECH with alcohol

Avoid excessive alcohol intake while taking METFORMIN BIOTECH since this may increase the risk of lactic acidosis (see Warnings and precautions).

Pregnancy, breastfeeding and fertility

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.

Do not take METFORMIN BIOTECH if you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent METFORMIN BIOTECH may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which METFORMIN BIOTECH affects you.

METFORMIN BIOTECH on its own does not cause hypoglycaemia (a blood glucose level which is too low). This means that it will not affect your ability to drive or use machines. However, take special care if you take METFORMIN BIOTECH together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do

not drive or use machines if you start to feel these symptoms.

METFORMIN BIOTECH 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 medicine.

3. How to take METFORMIN BIOTECH

Do not share medicines prescribed for you with any other person.

Always take METFORMIN BIOTECH exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take METFORMIN BIOTECH with or after a meal. This will avoid you having side effects affecting your digestion.

The usual dose is METFORMIN 850 BIOTECH twice a day or METFORMIN 500 BIOTECH three times a day.

If you are elderly your doctor will adjust the dose based on renal function.

If you are older than 12 years your doctor will prescribe a dose according to your blood glucose measurements.

Do not crush or chew the tablets. Swallow each tablet with a glass of water.

If you take one dose a day, take it in the morning (breakfast).

If you take two divided doses a day, take them in the morning (breakfast) and evening (dinner).

If you take three divided doses a day, take them in the morning (breakfast), at noon (lunch) and in the

evening (dinner).

Your doctor will tell you how long your treatment with METFORMIN BIOTECH will last. Do not stop treatment early because you feel better. If you have the impression that the effect of METFORMIN BIOTECH is too strong or too weak, tell your doctor or pharmacist.

If you take more METFORMIN BIOTECH than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take METFORMIN BIOTECH

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

If you stop taking METFORMIN BIOTECH

Do not stop taking METFORMIN BIOTECH without talking to your doctor first. Your blood sugar levels will be uncontrolled if you stop taking METFORMIN BIOTECH.

4. Possible side effects

METFORMIN BIOTECH can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in

swallowing or breathing,

- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to METFORMIN BIOTECH. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly. Symptoms of lactic acidosis are non-specific (see Warning and precautions)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- bellyache (abdominal pain)
- loss of appetite

These side effects most often happen at the beginning of the treatment with METFORMIN BIOTECH. It helps if you spread the doses over the day and if you take Glucophage with or straight after a meal.

- changes in taste.
- low vitamin B12 levels in the blood.

Less frequent side effects:

- abnormalities in liver function tests or hepatitis (inflammation of the liver; this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes).

- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).

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

5. How to store METFORMIN BIOTECH

Store all medicines out of reach of children.

Store at or below 25° C in a well-closed container.

Do not remove tablets from original packaging until required for use.

Protect from light and moisture.

Do not use after the expiry date stated on the label / carton / bottle.

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 METFORMIN BIOTECH contains

- The active substance is metformin hydrochloride.

METFORMIN 500 BIOTECH contains 500 mg metformin hydrochloride.

METFORMIN 850 BIOTECH contains 850 mg metformin hydrochloride.

- The other ingredients are:

Tablet core: colloidal silicone dioxide, copolyvidone, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

Tablet coating: Opadry white OY- L-28900 consisting of: lactose monohydrate, macrogol 4 000, methylhydroxypropylcellulose, titanium dioxide (E171).

What METFORMIN BIOTECH looks like and contents of the pack

METFORMIN 500 BIOTECH: White, biconvex oblong film coated tablets, with a both sided score notch.

One side engraved “M/500”. The surface is faultless. L: 17,0 to 17,4 mm, B: 7,0 to 7,4 mm, H: 5,6 to 6,4 mm.

METFORMIN 850 BIOTECH: White, oblong film coated tablets. upside with “snap-tab” downside convex and engraved “M/850” and faultless surface. L: 19,0 to 19,4 mm, B: 8,0 to 8,4 mm.

METFORMIN 500 BIOTECH:

Plain Pouch PRP (Patient Ready Pack): Plain laminated pouch made up of outer side metalised polyethylene terephthalate (PET) and inner side white opaque polyethylene (PE). Open from bottom side and zip lock with perforation on top side.

Pack size: 56’s

White, opaque HDPE container with white, opaque screw type cap with induction sealing wad.

Pack size: 100’s

METFORMIN 850 BIOTECH:

Plain Pouch PRP (Patient Ready Pack): Plain laminated pouch made up of outer side metalised polyethylene terephthalate (PET) and inner side white opaque polyethylene (PE). Open from bottom side and zip lock with perforation on top side.

Pack size: 28’s

White, opaque HDPE container with white, opaque screw type cap with induction sealing wad.

Pack size: 60’s,84’s

Metformin 500 & 850 Biotech

(35/21.2/0093/4)

Each film-coated tablet contains metformin hydrochloride 500 mg or 850 mg respectively

Holder of Certificate of Registration

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