

PATIENT INFORMATION LEAFLET

BGMET

(Metformin Tablets BP 500 mg)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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2. What you need to know before you take BGMET
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1. What BGMET is and what is it used for

What Metformin hydrochloride is Metformin hydrochloride tablet contains metformin, a medicine to treat diabetes. It belongs to a group of medicines called biguanides.

Insulin is a hormone produced by the pancreas that makes your body take in glucose (sugar) from the blood. Your body uses glucose to produce energy or stores it for future use.

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 hydrochloride helps to lower your blood glucose to as normal a level as possible.

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

What Metformin hydrochloride is used for

Metformin hydrochloride 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 can take Metformin hydrochloride on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin). Children 10 years and over and adolescents can take Metformin hydrochloride on its own or together with insulin.

2. What you need to know before you take BGMET

Do not take Metformin hydrochloride

- if you are allergic to metformin hydrochloride or any of the other ingredients of this medicine
- if you have severely reduced kidney function.
- if you have liver problems
- 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 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.
- 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 are treated for 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.
- if you drink a lot of alcohol If any of the above applies to you, talk to your doctor, before you start taking this medicine. Please note the following particular risk of lactic acidosis: Make sure you ask your doctor for advice,
- 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
- you need to have major surgery You must stop taking Metformin hydrochloride for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Warnings and precautions

Talk to your doctor or pharmacist before taking Metformin hydrochloride

Risk of lactic acidosis

Metformin hydrochloride 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.

Metformin hydrochloride on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin hydrochloride 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, visions disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar. Stop taking Metformin hydrochloride 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 hydrochloride 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.

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

During treatment with Metformin hydrochloride, 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.

Other medicines and Metformin hydrochloride.

If you need to have an injection of contrast medicines that contain iodine into your bloodstream, for example for examinations such as X-ray or scan, you must stop taking Metformin hydrochloride tablets before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Metformin

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of Metformin hydrochloride. It is especially important to mention the following:

- medicines which increase urine production (diuretics)
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- beta-2 agonists such as salbutamol or terbutaline (used to treat asthma)
- corticosteroids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma)
- other medicines used to treat diabetes Metformin hydrochloride tablets with food drink and alcohol

Avoid excessive alcohol intake while taking Metformin hydrochloride since this may increase the risk of lactic acidosis.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

Driving and using machines

Metformin hydrochloride 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 hydrochloride tablets together with other medicines to treat diabetes that can cause hypoglycaemia (sulphonylureas, insulin, meglitinides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating,

fast heart beat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

3. How to take BETAFORM 1 gm SR

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

Metformin hydrochloride cannot replace the benefits of a healthy lifestyle. Continue to follow any advice about diet that your doctor has given you and get some regular exercise.

The recommended dose is:

Children 10 years and over and adolescents usually start with 500 mg or 850 mg Metformin hydrochloride tablets once a day.

The maximum daily dose is 2000 mg taken as 2 or 3 divided doses. Treatment of children between 10 and 12 years of age is only recommended on specific advice from your doctor, as experience in this age group is limited.

Adults usually start with 500 mg or 850 mg Metformin hydrochloride tablets two or three times a day. The maximum daily dose is 3000 mg taken as 3 divided doses.

If you take insulin too, your doctor will tell you how to start Metformin hydrochloride tablets.

Monitoring

- Your doctor will perform regular blood glucose test and adapt your dose of Metformin hydrochloride tablets to your blood glucose levels. Make sure that you talk to your doctor regularly. This is particularly important for children and adolescents or if you are an older person
- Your doctor will also check at least once a year how well your kidneys work. You may need more frequent checks if you are an older person or if your kidneys are not working normally

How to take Metformin hydrochloride tablets

Take the tablets with or after a meal. This will avoid you having side effects affecting your digestion. 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)

If, after some time, you think that the effect of Metformin hydrochloride is too strong or too weak, talk to your doctor or pharmacist.

If you take more Metformin hydrochloride tablets than you should

If you have taken more Metformin hydrochloride tablets than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. If this

happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Talk to your doctor or pharmacist straight away.

If you forget to take Metformin hydrochloride tablets

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur:

Metformin hydrochloride may cause a very rare (may affect up to 1 user in 10,000), but very serious side effect called lactic acidosis (see section “Warnings and precautions”). If this happens you must stop taking Metformin hydrochloride and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.

Very common: (may affect more than 1 in 10 people)

- digestive problems, such as feeling sick (nausea), being sick (vomiting), diarrhoea, bellyache (abdominal pain) and loss of appetite. These side effects most often happen at the beginning of the treatment with Metformin hydrochloride. It helps if you spread the doses over the day and if you take the tablets with or straight after a meal. If symptoms continue, stop taking Metformin hydrochloride tablets and talk to your doctor.

Common: (may affect up to 1 in 10 people)

- changes in taste.

Very rare: (may affect up to 1 in 10,000 people)

- lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly. Symptoms of lactic acidosis are vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing.
- skin reactions such as redness of the skin (erythema), itching or an itchy rash (urticaria).
- low vitamin B12 levels in the blood.
- 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). If this happens to you, stop taking this medicine.

Children and adolescents

Limited data in children and adolescents showed that adverse events were similar in nature and severity to those reported in adults.

5. How to store bgmet

Keep this medicine out of the sight and reach of children.

Store in dry place, below 30°C. Protected from light.

Do not use the tablets after the expiry date that is printed on the pack. The expiry date refers to the last day of the month. This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What BGMET looks like and contents of the pack:

10 Blister of 10 Tablets packed in a carton along with leaflet

Marketing Authorisation Holder:

BLISS GVS PHARMA LTD.

102, Hyde Park, Saki Vihar road, Andheri (E), Mumbai, India– 400 072.