Patient Information Leaflet

Metformin Hydrochloride Brown & Burk 500 mg Prolonged-release Tablets
Metformin Hydrochloride Brown & Burk 750 mg Prolonged-release Tablets
Metformin Hydrochloride Brown & Burk 1000 mg Prolonged-release Tablets
Metformin hydrochloride

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 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.

What is in this leaflet:

1. What Metformin Hydrochloride Prolonged-release Tablets is and what it is used for

Metformin Hydrochloride Prolonged-release Tablets contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides. Metformin hydrochloride is used for the treatment of "Type 2 diabetes" (non-insulin dependent diabetes) diabetes mellitus.

Metformin Hydrochloride Prolonged-release Tablets are used together with the diet and exercise to lower the risk of developing Type-2 diabetes in overweight adults, when diet and exercise alone for 3 to 6 months have not been enough to control blood glucose level (sugar). You are at high risk of developing Type 2 diabetes if you have additional conditions like high blood pressure, age above 40 years, an abnormal amount of lipids (fat) in the blood or a history of diabetes during the pregnancy.

The medicine is particularly effective if you are aged below 45 years, are very overweight, have high blood glucose levels after a meal or developed diabetes during pregnancy.

Metformin Hydrochloride Prolonged-release Tablets are used for the treatment of Type 2 diabetes when diet and exercise changes alone have not been enough to control your blood glucose (sugar). Insulin is a hormone that allows your body tissue to take glucose from the blood and use it for energy or for storage for future use. People with Type 2 diabetes do not

make enough insulin in their pancreas or their body does not respond properly to the insulin it does make. This causes a build-up of glucose in the blood which can cause a number of serious long-term problems so it is important that you continue to take your medicine, even though you may not have any obvious symptoms. Metformin Hydrochloride Prolonged-release Tablets make the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Metformin Hydrochloride Prolonged-release Tablets are associated with either a stable body weight or modest weight loss.

Metformin Hydrochloride Prolonged-release Tablets are specially made to release the drug slowly in your body and therefore are different to many other types of tablets containing metformin.

2. What you need to know before you take Metformin Hydrochloride Prolonged-release Tablets

Do not take Metformin Hydrochloride Prolonged-release Tablets if:

- you are allergic to Metformin Hydrochloride Prolonged-release Tablets or to any other ingredients of this medicine (listed in section 6). An allergic reaction may cause a rash, itching or shortness of breath.
- you have liver problems
- 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.
- you have been treated for acute heart problems or have recently had a heart attack or you have severe circulation problems or 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').
- You have a severe infection, such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to the kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- you have severely reduced kidney function
- you have lost too much of water from your body (dehydration). Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- you are a heavy drinker of alcohol.
- you are under 18 years of age.

Warnings and precautions:

Risk of lactic Acidosis

Metformin Hydrochloride Prolonged-release Tablets 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 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 Metformin Hydrochloride Prolonged-release Tablets 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 fluids than normal. Talk to your doctor for further instructions.

Stop taking Metformin Hydrochloride Prolonged-release Tablets and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this conditions may lead to coma.

Symptoms of lactic acidosis includes:
- 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 Prolonged-release Tablets 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 Prolonged-release Tablets.

During treatment with Metformin Hydrochloride Prolonged-release Tablets, 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 are older than 75 years, treatment with Metformin Hydrochloride Prolonged-release Tablets should not be started to lower the risk of developing type 2 diabetes.

You may see some remains of the tablets in your stools. Do not worry- this is normal for this type of tablet.

You should continue to follow any dietary advice that your doctor has given you and you should make sure that you eat carbohydrates regularly throughout the day.

Do not stop taking this medicines without speaking to your doctor.

Other medicines and Metformin Hydrochloride Prolonged-release Tablets

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, in the context of an X-ray or scan, you must stop taking Metformin

Hydrochloride Prolonged-release Tablets before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with Metformin Hydrochloride Prolonged-release Tablets.

Tell your doctor or pharmacist if you are taking or have recently taken 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 Prolonged-release Tablets. It is especially important to mention the following:

- Steroids such as prednisolone, mometasone, beclometasone.
- Medicines which increases urine production (diuretics (water tablets) such as furosemide).
- 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).
- Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure. Epinephrine is also included in some dental anaesthetics.
- Medicines that may changes the amount of Metformin Hydrochloride Prolonged-release Tablets in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib)

Metformin Hydrochloride Prolonged-release Tablets with alcohol

Avoid excessive intake of alcohol while taking Metformin Hydrochloride Prolonged-release Tablets since this may increase the risk of lactic acidosis (see section ‘Warnings and precautions’).

Pregnancy and breast-feeding

If you are pregnant think you may be pregnant or are planning to have a baby, speak your doctor in case any changes will be needed to your treatment or monitoring of your blood glucose levels.

Driving and using machines

Metformin Hydrochloride Prolonged-release Tablets taken on its own does not cause ‘hypos’ (symptoms of low blood sugar or hypoglycaemia, such as faintness, confusion and increased sweating) and therefore should not affect your ability to drive or use machinery.

You should be aware, however, that Metformin Hydrochloride Prolonged-release Tablets taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

Metformin Hydrochloride Brown & Burk contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per prolonged-release tablet, that is to say essentially ‘sodium-free’.

3. How to take Metformin Hydrochloride Prolonged-release Tablets

Your doctor may prescribe Metformin Hydrochloride Prolonged-release Tablets for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

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

Swallow the tablets whole with a glass of water, do not chew.

Recommended dose:
Usually you need to start treatment with 500 milligrams Metformin Hydrochloride Prolonged-release Tablets daily. After you have been taking Metformin Hydrochloride Prolonged-release Tablets for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligram of Metformin Hydrochloride Prolonged-release Tablets.

If you have reduced kidney function, your doctor may prescribe a lower dose.

Normally, you should take the tablets once a day, with your evening meal.

In some cases, your doctor may recommend that you take the tablets twice a day. Always take the tables with food.

If you take more Metformin Hydrochloride Prolonged-release Tablets than you should

If you take extra tablets by mistake you need not worry, but if your unusual symptoms, contact your doctor. If the overdose is large, lactic acidosis is more likely. Symptoms of lactic acidosis are non-specific, such as vomiting, bellyache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heartbeat. If you experience some of these symptoms, you should immediately seek medical attention, as lactic acidosis may lead to coma. Stop taking Metformin Hydrochloride Prolonged-release Tablets immediately and contact a doctor or the nearest hospital straightaway.

If you forget to take Metformin Hydrochloride Prolonged-release Tablets

Take it as soon as you remember with some food. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Metformin Hydrochloride Prolonged-release Tablets can cause side effects, although not everybody gets them. The following side effects may occur:

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

Metformin Hydrochloride Prolonged-release Tablets may cause abnormal liver function tests and hepatitis (inflammation of the liver) which may result in jaundice (may affect up to 1 in 10,000 people). If you develop yellowing of the eye and/or skin contact your doctor immediately.

Other possible side effects are listed by frequency as follows:

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

- Diarrhoea, nausea, vomiting, stomach ache or loss of appetite. If you get these, do not stop taking the tablet as these symptoms will normally go away in about 2 weeks. It helps if you take the tablets with or immediately after a meal.

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

- Taste disturbance
- Decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

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

- Skin rashes including redness, itching and hives.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metformin Hydrochloride Prolonged-release Tablets

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

Do not use them after the expiry date that is printed on the pack after "EXP:". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Metformin Hydrochloride Prolonged-release Tablets contain

The active substance is metformin hydrochloride.

500 mg: Each prolonged-release tablet contains 500 mg metformin hydrochloride equivalent to 390 mg metformin base.

750 mg: Each prolonged-release tablet contains 750 mg metformin hydrochloride equivalent to 585 mg metformin base.

1000 mg: Each prolonged-release tablet contains 1000 mg metformin hydrochloride equivalent to 780 mg metformin base.

The other ingredients are Povidone K-90F, Colloidal anhydrous silica, Carmellose sodium, Hypromellose 90SH, Microcrystalline Cellulose, Magnesium Stearate.

What Metformin Hydrochloride Prolonged-release Tablets look like and contents of the pack

500 mg: White to off white, round shaped, biconvex tablets, debossed on one side with “500” and other side plain with approximately 12.15 mm diameter.

750 mg: White to off white, capsule shaped, biconvex tablets, debossed on one side with '750' and on the other side plain. The tablets are approximately 20.0 mm in length and 9.6 mm in breadth.

1000 mg: White to off white, capsule shaped, biconvex tablets, debossed on one side with '1000' and on the other side plain. The tablets are approximately 22.6 mm in length and 10.6 mm in breadth.

The tablets are available in blister strips [Clear PVC Film, coated with PVdC and Aluminium Foil].

Pack size:
500mg:
20, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 180, 600 tablets in blister.

750 mg:
14, 20, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 180 or 600 tablets in blister.

1000 mg:
14, 20, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 180 or 600 tablets in blister.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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