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PACKAGE LEAFLET: INFORMATION FOR THE USER

Metformin 500mg & 850mg 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 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.

What is in this leaflet.

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

1. WHAT METFORMIN TABLETS IS AND WHAT IT IS USED FOR

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

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

Metformin Tablets 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 Tablets 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 Tablets on its own or together with insulin.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE METFORMIN TABLETS

Do not take Metformin Tablets
- if you are allergic (hypersensitive) to metformin or any of the other ingredients of this medicine (see 'What Metformin Tablets contains' in section 6)
- if you have liver problems
- if you have severely reduced kidney function
- 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 (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 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 drink a lot of alcohol

If any of the above applies to you, talk to your doctor, before you start taking this medicine.
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 blood stream
- You need to have major surgery

You must stop taking Metformin tablets for a certain period of time before and after 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
Risk of lactic acidosis
- Metformin may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of 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).

  If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Metformin 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 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 during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Metformin.

Metformin on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin 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.

During the treatment with Metformin, 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 Tablets
If you need to have an injection of contrast medium that contain iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Metformin 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 Tablets.

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

Metformin Tablets with alcohol
Avoid excessive alcohol intake while taking Metformin since this may increase the risk of lactic acidosis (see section “Warnings and precautions”).

Pregnancy and breast-feeding
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.

This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

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Driving and using medicines
Metformin 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 together with other medicines used 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 tablets contains Sodium:
Metformin tablets contains less than 1 mmol (23 mg) of sodium per tablet, that is to say it is essentially 'sodium-free.

3. HOW TO TAKE METFORMIN TABLETS

Always take Metformin Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Metformin cannot replace the benefits of a healthy lifestyle. Continue to follow any advice about your diet that your doctor has given you and get some regular exercise.
For **oral use** only. Metformin Tablets should be swallowed, without chewing, with half a glassful of water during or after meals.

The recommended dose is
Adults: the usual starting dose is 500mg or 850mg Metformin, two or three times a day during or after meals. The maximum daily dose is 3000mg taken as 3 divided doses.
Elderly: the starting dose will be determined after tests have been carried on your kidney function.
Children: Children 10 years and over and adolescents usually start with 500 mg or 850 mg Metformin once a day during meals or after meals. 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.
If you take insulin too, your doctor will tell you how to start Metformin.

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

Monitoring
- Your doctor will perform regular blood glucose test and will adapt your dose of Metformin 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 more frequent checks if you are an older person or if your kidneys are not working normally.

How to take Metformin 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 Tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more Metformin Tablets than you should
If you have taken more Metformin Tablets than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are non-specific such as vomiting, bellyache (abdominal pain) 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 seek immediately medical attention, as lactic acidosis may lead to coma. Stop taking Metformin Tablets immediately and contact a doctor or the nearest hospital straight away.**

If you forget to take Metformin 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, Metformin Tablets can cause side effects, although not everybody gets them. The following side effects may occur:
Metformin 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 Tablets and contact a doctor or the nearest hospital immediately,** as lactic acidosis may lead to coma.

Very common side effects (in 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. It helps if you spread the doses over the day and if you take metformin with or straight after a meal. **If symptoms continue, stop taking Metformin tablets and talk to your doctor.**

Common side effects (in less than 1 in 10 people)
- Changes in taste.

Very rarely reported side effects (in less than 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 non-specific (see section 'Warning and precautions')
- 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 Metformin and talk to your doctor.**
- Skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).
- Low vitamin B12 levels in the blood.

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this lea et. You can also report side effects directly via the Yellow Card Scheme: 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 TABLETS

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

Do not store above 25°C. Store in the original package and keep containers tightly closed.

Do not use the tablets after the expiry date which is stated on the label.

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Metformin Tablets contains
The **active** substance is Metformin hydrochloride.

The **other ingredients** are sodium starch glycollate, maize starch, povidone, colloidalanhydrous silica, magnesium stearate,hypromellose, titanium dioxide (E171),propylene glycol, macrogol 6000 and purifiedtalc.

What Metformin Tablets look like and the contents of the pack

Metformin Tablets are white round, biconvexfilm-coated tablets, embossed with either 'M500' (500mg) or 'M850' (850 mg) on one sideand plain on the other side.

Metformin 500mg Tablets are available inblister packs of 28, 84, and 504 tablets. Theyare also available in plastic securitaners of 500 tablets

Metformin 850mg tablets are available inblister packs of 28, 56, 60, 84, and 308tablets. They are also available in plastic securitaners of 300 tablets

(Not all pack sizes may be marketed)

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