Package leaflet: Information for the user

Metformin hydrochloride Milpharm 500 mg prolonged release tablets
Metformin hydrochloride Milpharm 750 mg prolonged release tablets
Metformin hydrochloride Milpharm 1000 mg prolonged release tablets

metformin hydrochloride

This medicine is intended for **adult** patients only

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

1. What Metformin hydrochloride Milpharm is and what it is used for

Metformin hydrochloride Milpharm contains the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of Type 2 (non-insulin dependent) diabetes mellitus.

Metformin is used together with 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 (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 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 is used for the treatment of Type 2 diabetes mellitus when diet and exercise changes alone have not been enough to control blood glucose (sugar). Insulin is a hormone that enables body tissues to take glucose from the blood and to 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 makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Metformin is associated with either a stable body weight or modest weight loss.

This medicine is specially made to release the drug slowly in your body and therefore are different to many other types of tablet containing metformin.

Polycystic ovary syndrome (PCOS) is a health condition that affects a woman's hormone levels, menstrual cycle, and ability to have children. Metformin is used in women with PCOS to stimulate ovulation (release of an egg from the ovaries) and subsequently the chance of getting pregnant, alone or together with other treatment options.

2. What you need to know before you take Metformin hydrochloride Milpharm

Do not take Metformin hydrochloride Milpharm
- If you are allergic to metformin or to any of the other ingredients of this medicine (listed in section 6). An allergic reaction may cause a rash, itching or shortness of breath.
- 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 have lost too much water from your body (dehydration). 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 have been treated for acute heart problems or have recently had a heart attack or have severe circulatory 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’)
- If you are a heavy drinker of alcohol.
- If you are younger than 18 years of age.

If any of the above applies to you, talk to your doctor, before you start taking this medicine.

Warnings and precautions
<u>Risk of lactic acidosis</u>
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 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).

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.

Talk to your doctor promptly for further instructions if:
- You are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
- You have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.
If you need to have major surgery, you must stop taking Metforminduring and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Metformin.

During 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.

If you are older than 75 years, treatment with Metformin 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 as 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 medicine without speaking to your doctor

Other medicines and Metformin
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 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 or pharmacist 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. It is especially important to mention the following:
- medicines which increase urine production (diuretics (water tablets) such as furosemide)
- 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)
- steroids such as prednisolone, mometasone, beclometasone
- 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 change the amount of metformin in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).

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

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

Women of childbearing potential:
Metformin can stimulate ovulation (release of an egg from the ovaries), in women who do not ovulate properly. Beware of an increased chance of becoming pregnant when using Metformin.

Driving and using machines
Metformin 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 taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

3. How to take Metformin hydrochloride Milpharm

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

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

Recommended dose
Usually you will start treatment with 500 milligrams Metformin daily. After you have been taking Metformin for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligrams of Metformin.

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 tablets with food.

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

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

Polycystic ovary syndrome (PCOS)
The usual dose is 1500-2000 mg metformin hydrochloride taken once a day with the evening meal. You should check with your doctor or pharmacist when to stop taking the medicine.

If you take more Metformin than you should
If you take extra tablets by mistake you need not worry, but if you have 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 heart beat. If you experience some of these symptoms, you should immediately seek medical attention, as lactic acidosis may lead to coma. Stop taking Metformin immediately and contact a doctor or the nearest hospital straightaway.

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

If you stop taking Metformin
You should not stop taking this medicine without talking to your doctor first. If you stop taking Metformin, your blood sugar may rise again.

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 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 and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

Metformin may cause abnormal liver function tests and hepatitis (inflammation of the liver) which may result in jaundice (may affect up to 1 user in 10,000). If you develop yellowing of the eyes 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 tablets 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 levels of vitamin B12 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 determine the cause of your symptoms, as some of them may also be caused by diabetes or 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at 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 Milpharm

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

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

This medicine 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 Metformin hydrochloride Milpharm prolonged release tablets contains
- The active substance is metformin hydrochloride.

Each prolonged release tablet contains 500 mg metformin hydrochloride.
Each prolonged release tablet contains 750 mg metformin hydrochloride.
Each prolonged release tablet contains 1000 mg metformin hydrochloride.

- The other ingredients are: Hypromellose, cellulose, microcrystalline (grade 101), povidone (K-90), magnesium stearate.

What Metformin hydrochloride Milpharm prolonged release tablets looks like and contents of the pack
Prolonged release tablet

Metformin hydrochloride Milpharm 500 mg prolonged release tablets
White to off-white, round, approximately 12mm uncoated tablets debossed with '500' on one side and plain on other side.

Metformin hydrochloride Milpharm 750 mg prolonged release tablets
White to off-white, capsule, approximately 19.3mm × 9.4mm uncoated tablets debossed with '750' on one side and plain on other side.

Metformin hydrochloride Milpharm 1000 mg prolonged release tablets
White to off-white, oval, approximately 22.2mm × 10.6mm uncoated tablets debossed with '1000' on one side and plain on other side.

Metformin hydrochloride Milpharm prolonged release tablets are available in blister packs of 28 and 56 prolonged release tablets.

Not all pack sizes may be marketed.

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