

PACKAGE LEAFLET: INFORMATION FOR THE USER

Metformin Hydrochloride 500 mg/5 ml Oral Solution
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 Oral Solution is and what it is used for
2. What you need to know before you take Metformin Oral Solution
3. How to take Metformin Oral Solution
4. Possible side effects
5. How to store Metformin Oral Solution
6. Contents of the pack and other information

1. WHAT METFORMIN ORAL SOLUTION IS AND WHAT IT IS USED FOR

What Metformin Oral Solution is

Your medicine is called 'Metformin Hydrochloride 500 mg/5 ml Oral Solution'. It will be referred to throughout this leaflet as 'Metformin Oral Solution'. Metformin Oral Solution 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 properly use the insulin it produces. This leads to a high level of glucose in your blood. Metformin Oral Solution helps to lower your blood glucose to as normal a level as possible.

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

What Metformin Oral Solution is used for

Metformin Oral Solution 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 Oral Solution 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 Oral Solution on its own or together with insulin.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE METFORMIN ORAL SOLUTION

Do NOT take Metformin Oral Solution

- if you are allergic (hypersensitive) to metformin or any of the other ingredients of this solution (see section 6 and end of section 2)
- 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. The symptoms of ketoacidosis 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), 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 kidneys. 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 of lactic acidosis (see "Warnings and precautions" below)
- 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.

Talk to your doctor before taking Metformin Oral Solution if:

- you need to have an examination such as X-ray or scan involving iodine contrast medicines that contain iodine in your bloodstream
- you need to have major surgery.

You must **stop** taking Metformin Oral Solution 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

Risk of lactic acidosis.

Metformin Oral Solution may cause a very rare, but serious complication 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 diseases). If any of the above apply to you, talk to your doctor for further instructions.

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

Metformin Oral Solution on its own does not cause hypoglycaemia (low blood glucose level). However, if you take Metformin Oral Solution with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas e.g. gliclazide, insulin, meglitinides e.g. repaglinide), 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 treatment with Metformin Oral Solution, 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.

Patients with heart failure are more at risk of hypoxia and renal insufficiency. If you have stable chronic heart failure, your doctor will check your heart and kidney function regularly. Do not take Metformin Oral Solution if you have acute or unstable heart failure.

The diagnosis of type II diabetes must be confirmed before children and adolescents are treated with metformin. No effects of metformin on the growth and puberty of children has been observed, however monitoring of children is recommended.

Caution is recommended when prescribing to children aged between 10 and 12 years.

Other medicines and Metformin Oral Solution

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, **you must stop taking Metformin Oral Solution before or at the same time of injection**. Your doctor will decide when you must stop and when to restart your treatment with Metformin Oral Solution.

Tell your doctor if you are taking, have recently taken or might take any other medicine. You may need more frequent blood glucose and kidney function tests, or your doctor may adjust the dosage of Metformin Oral Solution. 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 Oral Solution in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin; cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib)
- other medicines to treat diabetes mellitus.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Metformin Oral Solution with alcohol

Avoid excessive alcohol intake while taking Metformin Oral Solution since this may increase the risk of lactic acidosis (see section "Warnings and precautions"). This also applies to medicines that contain alcohol, including those obtained without a prescription.

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.

Driving and using machines

Metformin Oral Solution on its own does not cause hypoglycaemia (low blood glucose). This means that it will not affect your ability to drive or use machines.

However, take special care if you take Metformin Oral Solution together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas e.g. gliclazide, insulin, meglitinides e.g. repaglinide). 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.

Metformin Oral Solution contains methyl and propyl parahydroxybenzoate, liquid maltitol, sodium and ethanol

- Methyl and propyl parahydroxybenzoate – may cause allergic reactions (possibly delayed).
- Liquid maltitol - if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May have a mild laxative effect. Calorific value 2.3 kcal/g of maltitol.
- Sodium - 14.19 mg per 5 ml dose. This should be taken into consideration for patients on a controlled sodium diet.
- Ethanol - This medicinal product contains small amounts of ethanol (alcohol) less than 100 mg per 5 ml.

3. HOW TO TAKE METFORMIN ORAL SOLUTION

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

If you also take insulin, your doctor will tell you how to start taking Metformin Oral Solution.

The recommended dose is

Adults

- The recommended starting dose of Metformin Oral Solution is 5 ml (500 mg) or 8.5 ml (850 mg) two or three times a day
- The maximum daily dose is 30 ml (3000 mg) taken as 3 divided doses.

For the elderly (where decreased renal function is likely), the dosage should be adjusted based on renal function.

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

Use in Children 10 years and over and adolescents

- The recommended starting dose of Metformin Oral Solution is 5 ml (500 mg) or 8.5 ml (850 mg) once a day
- The maximum daily dose is 20 ml (2000 mg) taken as two or three 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.

Directions for using the syringe:

1. Open the bottle
2. Insert the adaptor into the bottle neck and ensure it is well fixed.
3. Push the tip of the syringe firmly into the adaptor plug (hole) in the neck of the bottle. When in position the tip should be partly visible. Do not force it all the way in.
4. To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down slowly drawing the medicine to the correct mark (5 ml, 8.5 ml or 10 ml) on the syringe.
5. Turn the bottle the right way up, and then gently twist the syringe to remove from the adaptor plug.
6. Place the end of the syringe into your mouth, pressing the plunger down to slowly and gently release the medicine.

After use replace the cap on the top of the bottle tightly. The adaptor should remain in the bottle. Wash the syringe in warm water and allow to dry.

Monitoring

- Your doctor will perform regular blood glucose tests and will adapt your dose of Metformin Oral Solution 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 Oral Solution

Take Metformin Oral Solution with or after a meal. This will help to avoid any side effects affecting your digestion.

- 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 you think that the effect of Metformin Oral Solution is too strong or too weak, talk to your doctor or pharmacist.

If you take more Metformin Oral Solution than you should

If you have taken more Metformin Oral Solution than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are vomiting, 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 immediate medical attention, as lactic acidosis may lead to coma. Stop taking Metformin Oral Solution and contact a doctor or the nearest hospital straight away.**

If you forget to take Metformin Oral Solution

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

If you stop taking Metformin Oral Solution

Keep taking this medicine until your doctor tells you to stop.

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:

Serious side effects

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

Other side effects

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

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

Common side effects (may affect up to 1 in 10 people)

- changes in taste
- 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 side effects (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 non-specific (see section “Warnings 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 Oral Solution and talk to your doctor.**
- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).

Additional side effects in 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, 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 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 ORAL SOLUTION

Keep this medicine out of the sight and reach of children. If a child is treated with Metformin Oral Solution, parents and caregivers are advised to oversee how this medicine is used.

Do not store above 25°C.

Do not take Metformin Oral Solution 60 days after opening the bottle and discard any remaining medicine. Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist about this.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Metformin Oral Solution contains

- The **active substance is:** metformin hydrochloride. Each 5 ml dose of Metformin Oral Solution contains 500 mg of metformin hydrochloride.
- The **other ingredients** are: liquid maltitol (E965), glycerol (E422), saccharin sodium (E954), propylene glycol (E1520), propyl parahydroxybenzoate (E216), methyl parahydroxybenzoate (E218), sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate (E339), peppermint flavour (contains ethanol), peach flavour (contains propylene glycol and ethanol), hydrochloric acid (for pH adjustment) and purified water (*See end of Section 2 for further information*).

What Metformin Oral Solution looks like and contents of the pack

Metformin Oral Solution is a clear, colourless peach and peppermint flavoured oral solution presented in 100 ml and 150 ml amber glass bottles with child-resistant closures. A 10 ml graduated dosing syringe is provided.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Limited, Ballymacarby, Clonmel, Co. Tipperary, Ireland. PL Number: PL 04917/0094

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