

Patient Information Leaflet

Read all of this leaflet carefully before you start using this medicine.

- * 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 symptoms are the same as yours.
- * If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 What Metformin Hydrochloride Oral Solution is and what it is used for

What Metformin is

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

If you are an overweight adult, taking Metformin over a long period of time also helps to lower the risk of complications associated with diabetes.

What Metformin is used for

Metformin 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 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 on its own or together with insulin.

2 Before you take Metformin Hydrochloride Oral Solution

Do not take Metformin Hydrochloride Oral Solution:

- * If you are allergic (hypersensitive) to metformin or any of the other ingredients of this liquid (see 'What Metformin Hydrochloride Oral Solution contains' in section 6)
- * if you have liver or kidney problems
- * if you have uncontrolled diabetes, such as severe hyperglycaemia (a blood glucose level which is too high) or ketoacidosis which can lead to diabetic pre-coma. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood. Symptoms include stomach pain, fast and deep breathing, sleepiness or unusual fruity odour of the breath
- * 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 'Take special care with Metformin' below)
- * 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 'Take special care with Metformin' below)
- * 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 of lactic acidosis (see 'Take special care with Metformin' below)
- * if you drink a lot of alcohol
- * if you are breast-feeding.

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 bloodstream
- * you need to have major surgery.

You must stop taking metformin 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.

Take special care with Metformin

Metformin may cause a very rare, but serious complication called lactic acidosis, particularly if your kidneys are not working properly. The risk of lactic acidosis is also increased with uncontrolled diabetes mellitus, prolonged fasting or alcohol intake. 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. Stop taking metformin immediately and contact your doctor or nearest hospital straight away.**

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 sulfonyleureas, insulin, glinides), 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.

Taking other medicines

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

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 for a certain period of time before and after the examination** (see 'Make sure you ask your doctor for advice' above).

Tell your doctor if you take any of the following medicines and metformin at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of metformin:

- * angiotensin-converting enzyme inhibitors (used to treat a variety of heart and blood vessel conditions, such as high blood pressure or heart failure)
- * diuretics (used to remove water from the body by making more urine)
- * 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 to treat diabetes mellitus.

Taking Metformin Hydrochloride Oral Solution with food and drink

Do not drink alcohol when you take this medicine. Alcohol may increase the risk of lactic acidosis especially if you have liver problems, if you are undernourished or if you have been fasting for a long time. This also applies to medicines that contain alcohol.

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.

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 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 to treat diabetes that can cause hypoglycaemia (such as sulfonyleureas, insulin, glinides). 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.

Important information about some of the ingredients of Metformin Hydrochloride Oral Solution

This medicine contains:

- * Sodium methyl and propyl parahydroxybenzoates. These may cause an allergic reaction such as skin rash and difficulty in breathing. If this happens talk to a doctor straight away
- * Liquid maltitol. If your doctor has told you that you cannot tolerate some sugars, talk to your doctor before taking this medicine. It may have a mild laxative effect. Calorific value is 2.3kcal/g maltitol
- * Sodium (5.3mg in a 5ml dose). Take this into account if you are on a low sodium diet
- * Potassium (14.5mg in a 5ml dose). Take this into account if you have kidney problems or are on a low potassium diet.

3 How to take Metformin Hydrochloride Oral Solution

Always take Metformin Hydrochloride Oral Solution 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 diet that your doctor has given you and get some regular exercise.

Patient Information Leaflet (continued)

Usual Dose

Children over 10 and adolescents

- * The usual dose of metformin is one 5ml spoonful (500mg) each day
- * Do not give more than a total of four 5ml spoonful (2g) of metformin in one day (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

- * The usual starting dose is one 5ml spoonful (500mg) two or three times a day
- * Do not take more than a total of six 5ml spoonful (3g) of metformin in one day (taken as 3 divided doses).

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

Monitoring

- * Your doctor 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 frequent checks if you are an older person or if your kidneys are not working normally.

How to take Metformin Hydrochloride Oral Solution

Take the liquid with or after a meal. This will avoid you having 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, after some time, you think that the effect of metformin is too strong or too weak, talk to your doctor or pharmacist.

If you take more Metformin Hydrochloride Oral Solution than you should

Talk to a doctor or go to a hospital straight away. If you have taken more metformin 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 you forget to take Metformin Hydrochloride Oral Solution

Take it as soon as you remember. However, if it is less than 2 hours away from the next dose, skip the missed dose. Then go on as before. Do not take a double dose to make up for the forgotten dose.

If you stop taking Metformin Hydrochloride Oral Solution

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

4 Possible side effects

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

If you get any of the following very rare side effects, stop taking metformin and see your doctor immediately:

- * lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly. If you get this complication, you will need immediate treatment. 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, stop taking metformin immediately and tell your doctor straight away.**

Other side effects:

Very common (affects 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 the medicine with or straight after a meal. **If symptoms continue, stop taking metformin and talk to your doctor.**

Common (affects more than 1 in 100 people)

- * changes in taste.

Very rare (affects less than 1 in 10,000 people)

- * skin reactions such as redness of the skin (erythema), itching or an itchy rash (urticaria)
- * low vitamin B12 levels in the blood.

The frequencies of the following side effects are not known:

- * 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.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5 How to store How to store Metformin Hydrochloride Oral Solution

- * Keep out of the reach and sight of children
- * Do not store above 25°C
- * Get rid of the medicine 28 days after first opening
- * Do not use after the expiry date which is stated on the label and carton EXP (month,year). The expiry date refers to the last day of that month
- * Do not use Metformin Hydrochloride Oral Solution if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist
- * 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 Further information

What Metformin Hydrochloride Oral Solution contains

The active substance is Metformin Hydrochloride.

Each 5ml oral solution contains 500mg Metformin Hydrochloride.

1ml of oral solution contains 100mg Metformin Hydrochloride.

The other ingredients are sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), liquid maltitol (E965), sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate anhydrous (E339), acesulfame potassium (E950), ammonia caramel (E150c), peppermint flavour (containing propylene glycol, isopropyl alcohol and pulegone), peach flavour (containing propylene glycol and isopropyl alcohol) and purified water.

What Metformin Hydrochloride Oral Solution looks like and contents of the pack

Metformin Hydrochloride Oral Solution is a clear brown liquid which is peach and mint flavoured. It comes in a brown glass bottle holding 150ml of solution.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18 Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Re-packaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Manufactured by:

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

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for help.