

## Package leaflet: Information for the patient

### Metformin Hydrochloride 500mg/5ml Oral Solution

**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 your pharmacist.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their symptoms 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 Oral Solution is and what it is used for
2. What you need to know before you take Metformin Hydrochloride Oral Solution
3. How to take Metformin Hydrochloride Oral Solution
4. Possible side effects
5. How to store Metformin Hydrochloride Oral Solution
6. Contents of the pack and other information

### **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. What you need to know 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 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), 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' 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 'Warnings and Precautions' 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 '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.

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.

### 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 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.

*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.

**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 sulfonylureas, 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 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**

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

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. 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 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.

### **Metformin with alcohol**

Avoid excessive alcohol intake whilst taking this medicine 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.

### **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 sulfonylureas, 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 Oral Solution contains sodium methyl and propyl parahydroxybenzoates, liquid maltitol and propylene glycol.

- sodium methyl (E219) and propyl parahydroxybenzoates (E217). May cause allergic reactions (possibly delayed).
- liquid maltitol (E965). 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 is 2.3kcal/g maltitol.
- This medicine contains less than 1mmol of sodium (23mg) per 5ml or 10ml dose, that is to say essentially “sodium free”.
- This medicine contains potassium, less than 1mmol (39mg) per 5ml or 10ml dose, i.e., essentially “potassium-free”.
- propylene glycol (E1520) – This medicine contains 7.7mg propylene glycol in each 5ml dose and 15.4mg in each 10ml dose.

### **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.

#### **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 have reduced kidney function, your doctor may prescribe a lower dose.

In renal impaired patients with GFR between 45 and 60 ml/min the starting dose is 500mg, once daily. The maximum dose is 1000 mg daily given in two divided doses. The renal function should be closely monitored (every 3-6 months).

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 that 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. 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 Hydrochloride immediately and contact a doctor or the nearest hospital straight away.**

## **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.

**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 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.

### **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
- 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 (affects less than 1 in 10,000 people)**

- skin reactions such as redness of the skin (erythema), itching or an itchy rash (urticaria).
- abnormalities in liver function test 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 hydrochloride and talk to your doctor.**

**Children and adolescents**

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**Ireland**

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

## **5. How to store Metformin Hydrochloride Oral Solution**

- Keep out of the sight and reach of children.
- Store in a refrigerator (2-8°C).
- Get rid of the medicine 28 days after 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. Contents of the pack and other 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 (E1520), isopropyl alcohol and pulegone), peach flavour (containing propylene glycol (E1520) 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 100ml or 150ml of solution.

### **Marketing Authorisation Holder:**

Taw Pharma (Ireland) Ltd,  
104 Lower Baggot Street,  
Dublin 2, D02 Y940,  
Ireland.

### **Manufacturer:**

Jenson R+ (Ireland) Ltd, Unit 15, Daingean Hall, N4 Axis Centre, Longford,  
N39 W6K0, Ireland.

### **This medicinal product is authorised in the Member States of the EEA and United Kingdom (Northern Ireland) under the following names:**

United Kingdom/Ireland	Metformin Hydrochloride 500mg/5ml Oral Solution
Greece	Metformin Hydrochloride/Rosemont Πόσιμο διάλυμα 500 mg/5ml

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