

Package leaflet: Information for the user

Metformin Colonis 500 mg/5ml 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

- Metformin Colonis 500 mg/5ml Oral Solution (referred to as Metformin Oral Solution in this leaflet) contains metformin hydrochloride, a medicine to **treat diabetes**. It belongs to a group of medicines called biguanides.
- After you have eaten, your body converts the carbohydrates and sugar in your food into glucose, which travels in your blood to where it is needed. Insulin is a hormone produced in your pancreas which moves the glucose from your blood into your body's cells where it is used as energy (fuel).
- If you have type 2 diabetes, your pancreas does not make enough insulin or your body is not able to use properly the insulin it produces, (known as insulin resistance). This leads to high levels of glucose in your blood. Metformin Oral Solution helps to lower your blood glucose to as normal a level as possible.
- This medicine 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 often used in overweight patients.
- If you are an overweight adult, taking this medicine over a long period of time can also help lower the risk of complications associated with diabetes. This medicine is associated with either a stable body weight or modest weight loss.
- **Adults** can take this medicine on its own or together with other medicines to treat diabetes or with insulin.
- **Adolescents and children aged 10 years and over** can take this medicine 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 hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have **uncontrolled diabetes**, with e.g. severe hyperglycaemia (high levels of blood glucose in your blood), nausea (feeling sick), vomiting (being sick), dehydration or rapid weight loss

- if you have symptoms of a condition called **ketoacidosis** in which substances called 'ketone bodies' accumulate in the blood and can lead to diabetic pre-coma (unconsciousness). Symptoms include **stomach pain, fast and deep breathing, sleepiness and unusual fruity odour of the breath** (likened to the smell of pear drops)
- if you have moderate or severe **liver or kidney problems**
- if you become **dehydrated** (when you lose too much water from your body), due to long-lasting or **severe diarrhoea**, or if you have been **sick several times** in a short space of time. Dehydration may lead to kidney problems, which can put you at risk of lactic acidosis (see 'Warnings and precautions')
- if you have a **severe infection**, such as an infection affecting your lungs, airways or your kidneys. Severe infections may lead to kidney problems, which can put you at risk of lactic acidosis (see 'Warnings and precautions' and Section 4 Possible side effects)
- 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 of oxygen in your body tissues which can put you at risk of 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.

Warnings and precautions

- Metformin Oral Solution may cause a very rare, but very serious complication called **lactic acidosis**, particularly if your **kidneys are not working properly** (kidney function may worsen when starting medication for high blood pressure, water retention and when starting treatment with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
- 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
 - any medical conditions in which a region of the body is deprived of oxygen (such as acute severe heart diseases).

Stop taking this medicine 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.

It is important you take your medication as prescribed, follow dietary instructions and keep up your regular exercise program because these measures can reduce the risk of lactic acidosis.

- The onset of **lactic acidosis** can be subtle and the **symptoms** can be non-specific such as:
 - being sick (vomiting)
 - stomach ache (abdominal pain)
 - muscle cramps
 - a general feeling of not being well with severe tiredness
 - difficulty in breathing
 - further symptoms are reduced body temperature and heartbeat.

If you experience some of these symptoms, stop taking this medicine and seek medical attention immediately.

- 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.
- Talk to your doctor or pharmacist before using Metformin Oral Solution if:
 - you need to have a diagnostic examination such as **X-ray or scan** involving the injection of **contrast dyes** that contain iodine into your bloodstream
 - you need to have **surgery** in which you will be given an **anaesthetic** (put to sleep).

You must **stop taking** Metformin Oral Solution for a certain period of time **before** and **after** the examination or surgery. Your doctor will tell you what you need to do and will decide whether you need any other treatments during this time. It is important that you follow your doctor's instructions precisely.

On its own this medicine does not cause **hypoglycaemia** (a condition when your **blood glucose** levels become **too low**). However, if you take Metformin Oral Solution **together with other medicines used to treat diabetes** (such as sulphonylureas, insulin, meglitinides), there is a risk of hypoglycaemia. If you **experience symptoms** 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**.

Children aged 10 and over and adolescents

- This medicine may be used in children **aged 10 and over** either by itself or in combination with insulin.
- **Regular monitoring** of children taking this medicine is **recommended**.

Other medicines and Metformin Oral Solution

- If you need to have an injection of a contrast dye medicine that contains iodine for a diagnostic examination such as an X-ray or scan, you will need to **stop taking** Metformin Oral Solution for a period of time both **before and after the examination (at least 48 hours)**. It is important that you **discuss this with your doctor beforehand**.
- **Tell your doctor** or pharmacist if you are taking, have recently taken or might take any other medicines, including those bought without a prescription.
- You may need more frequent blood glucose tests or your doctor may adjust the dosage of Metformin Oral Solution if you are taking or have recently taken:
 - **diuretics** (used to remove water from the body by making more urine)
 - medicines used to treat pain and inflammation (**NSAID** and **COX-2-inhibitors**, such as ibuprofen, diclofenac and celecoxib)
 - medicines to treat **high blood pressure** (**ACE inhibitors** and **angiotensin II receptor antagonists**)
 - **beta-2 agonists** such as salbutamol or terbutaline (used to treat asthma)
 - **corticosteroids** such as prednisolone (used to treat a variety of conditions including asthma and inflammation)
 - 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 used to treat **diabetes**.

Metformin 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 or if you are undernourished. This also applies to medicines that contain alcohol.

Pregnancy and breast-feeding

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask 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

- Taken on its own this medicine does not cause hypoglycaemia (a condition where your blood glucose levels become too low). This means that it will not affect your ability to drive or use machines.
- If this medicine is taken with insulin or other medicines used to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin and meglitinides), it is possible that their **combined effects may make you feel faint or dizzy**. Other symptoms of hypoglycaemia include weakness, increased sweating, fast heartbeat, vision disorders and difficulty concentrating. If you experience any of these symptoms **do not drive or operate machinery** until you feel better.

Metformin Oral Solution contains sodium propyl parahydroxybenzoate (E217), propylene glycol (E1520), ethanol and sodium

- Parahydroxybenzoates may cause allergic reactions (possibly delayed).
- This medicine contains 16.5 mg propylene glycol in each 5 ml.
- This medicine contains 5.4 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains 5.6 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.28% of the recommended maximum daily dietary intake of sodium for an adult.

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. You should continue to follow any advice about diet that your doctor has given you and take regular exercise.

Recommended dose

Children and adolescents aged 10 years and over

- The recommended starting dose for children is either 500 mg (5 ml) or 850 mg Metformin Oral Solution once a day.
- The maximum daily dose is 2000 mg (20 ml) 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 knowledge of the effects of this medicine in this age group is limited.

Adults

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

Adults with kidney problems

- The recommended starting dose for adults with kidney impairment is 500 mg (5 ml) or 850 mg Metformin Oral Solution once a day.
- The maximum dose is 1000 mg (10 ml) daily, given as 2 divided doses.
- Kidney function should be closely monitored every 3 - 6 months.

Note: Metformin Oral Solution 500 mg/5 ml is intended for the administration of doses of 500 mg or multiples of 500 mg.
850 mg/5 ml and 1000 mg/5 ml strengths are also available and can be used to ensure the right dose to control your symptoms is achieved. If you think this would be beneficial to you talk to your doctor.

If you also take insulin your doctor will give you advice about how to take this medicine with your insulin.

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 how well your **kidneys** are working **at least once a year**. You may need more frequent checks if you are an older person or if your kidneys are not working normally.

Directions for use

- Always take this medicine **with or after a meal**. This may help you avoid having some of the side effects.
- If you take **one dose a day**, take it in the morning (breakfast).
- If you have been advised to take **two doses a day**, take them in the morning (breakfast) and evening (dinner).
- If you have been advised to take **three 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 this medicine is too strong or too weak, talk to your doctor or pharmacist.
- Use the graduated 10 ml dosing spoon provided to administer the correct dose.

Method of administration

Metformin Oral Solution is for oral use only.

Note

If necessary, Metformin Oral Solution can be administered via a gastric, duodenal, and nasal feeding tube, that should be rinsed twice with 10 ml of water immediately after administration.

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**, (see Section 4 Possible side effects). This is a very serious medical condition and you should stop taking this medicine and **seek medical advice immediately** because it can lead to **coma**.

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 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.

Stop taking Metformin Oral Solution and **see a doctor or go to a hospital straight away** if you experience any of these very rare side effects (may affect up to 1 in 10,000 people)

- **Lactic acidosis:** lactic acidosis is a very rare side effect (may affect up to 1 in 10,000 people) but is a very serious complication particularly if your kidneys are not working properly. Lactic acidosis can be subtle and the symptoms can be non-specific such as:
 - being sick
 - stomach ache (abdominal pain) with muscle cramps
 - a general feeling of not being well with severe tiredness
 - difficulty in breathing
 - reduced body temperature (hypothermia)
 - slower heartbeat.

If you experience these symptoms, you should **seek medical advice immediately**, because **lactic acidosis** may lead to **coma**, even if you have not had problems with this medicine before.

- **Liver function:** abnormalities in **liver function** tests or **hepatitis** (inflammation of the liver) may cause:
 - tiredness
 - loss of appetite
 - weight loss
 - possible yellowing of your skin or the whites of your eyes.

If this happens to you, **stop taking Metformin Oral Solution and talk to your doctor straight away**.

Very Common (may affect more than 1 in 10 people):

These side effects happen most often at the beginning of treatment with Metformin Oral Solution. It helps if you **spread the doses** out over the day and if you take this medicine **with or straight after a meal**. If symptoms continue, stop taking Metformin Oral Solution and talk to your doctor

- feeling or being sick
- diarrhoea
- stomach ache (abdominal pain)
- loss of appetite.

Common (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 (may affect up to 1 in 10,000 people):

- skin reactions such as redness of the skin (erythema)
- itching or an itchy rash (hives).

Children and adolescents

Limited data in children and adolescents showed that side effects 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 leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in 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 this medicine is intended for use in a child, administration of the medicine should be supervised by an adult.

- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the bottle and carton after 'EXP'. The expiry date refers to the last day of that month.
- **Once the bottle has been opened, this medicine should be used within 2 months.**
- 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 Oral Solution contains

- The active substance is metformin hydrochloride. Each 5 ml oral solution contains 500 mg of metformin hydrochloride.
- The other ingredients are:
 - Sodium propyl parahydroxybenzoate (E217)
 - Sodium dihydrogen phosphate dihydrate (E339)
 - Disodium phosphate anhydrous (E339)
 - Sucralose (E955)
 - Peach flavour (contains propylene glycol (E1520) and ethanol)
 - Sodium hydroxide (E524), (for pH adjustment)
 - Purified water.

What Metformin Oral Solution looks like and contents of the pack

Metformin Oral Solution is a clear, colourless solution with a peach flavour, filled into 150 ml or 300 ml, amber glass bottles fitted with a child-resistant, tamper-evident screw cap.

Not all pack sizes may be marketed.

A graduated 10 ml dosing spoon is also included in the pack.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Colonis Pharma Limited
25 Bedford Square,
Bloomsbury,
London,
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United Kingdom.

Manufacturers:

Rafarm S.A.
Thesi Pousi-Xatzi,
Agiou Louka,
Paiania Attiki,
TK19002,
TΘ 37,
Greece.

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