



PACKAGE LEAFLET: INFORMATION FOR THE USER

Metformin hydrochloride 500 mg film-coated tablets Metformin hydrochloride 850 mg film-coated tablets Metformin hydrochloride 1000 mg film-coated tablets Metformin hydrochloride

Read all of this leaflet carefully before you start taking 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Metformin hydrochloride is and what it is used for
2. Before you take Metformin hydrochloride
3. How to take Metformin hydrochloride
4. Possible side effects
5. How to store Metformin hydrochloride tablets
6. Further information

1. WHAT METFORMIN HYDROCHLORIDE IS AND WHAT IT IS USED FOR

What Metformin hydrochloride is

Metformin hydrochloride tablet 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 use properly the insulin it produces. This leads to a high level of glucose in your blood. Metformin hydrochloride helps to lower your blood glucose to as normal a level as possible.

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

What Metformin hydrochloride is used for

Metformin hydrochloride 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 hydrochloride 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 hydrochloride on its own or together with insulin.

2. BEFORE YOU TAKE METFORMIN HYDROCHLORIDE

Do not take Metformin hydrochloride

- if you are allergic (hypersensitive) to Metformin hydrochloride or any of the other ingredients of this medicine (see 'What Metformin hydrochloride tablet contains' in section 6)
- if you have kidney or liver problems
- if you have uncontrolled diabetes, such as severe hyperglycaemia or ketoacidosis. 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 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 hydrochloride' below)
- 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 'Take special care with Metformin hydrochloride' below)
- if you are treated for heart failure or have recently had a heart attack, have severe problems with your circulation or have breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see 'Take special care with Metformin hydrochloride' 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 hydrochloride 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 hydrochloride

Metformin hydrochloride may cause a very rare, but serious complication called lactic acidosis, particularly if your kidneys are not working properly. 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 treatment. Stop taking Metformin hydrochloride tablets immediately and tell your doctor straight away.**

Metformin hydrochloride on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin hydrochloride together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, glinides), there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, visions disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

Taking other medicines

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 hydrochloride tablets 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 hydrochloride tablets at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of Metformin hydrochloride:

- 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)

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

Taking Metformin hydrochloride tablets 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

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 hydrochloride 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 hydrochloride tablets together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, 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.

3. HOW TO TAKE METFORMIN HYDROCHLORIDE

Always take Metformin hydrochloride tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Metformin hydrochloride 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 10 years and over and adolescents usually start with 500 mg or 850 mg Metformin hydrochloride tablets once a day. The maximum daily dose is 2000 mg 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 usually start with 500 mg or 850 mg Metformin hydrochloride tablets two or three times a day. The maximum daily dose is 3000 mg taken as 3 divided doses.

If you take insulin too, your doctor will tell you how to start Metformin hydrochloride tablets.

Monitoring

- Your doctor will adapt your dose of Metformin hydrochloride tablets 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 tablets

Take the tablets with or after a meal. This will avoid you having side effects affecting your digestion.

Do not crush or chew the tablets. Swallow each tablet with a glass of water.

- 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 hydrochloride is too strong or too weak, talk to your doctor or pharmacist.

If you take more Metformin hydrochloride tablets than you should

If you have taken more Metformin hydrochloride tablets 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. Talk to your doctor or pharmacist straight away.

If you forget to take Metformin hydrochloride tablets

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Very common side effects (in 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 hydrochloride. It helps if you spread the doses over the day and if you take the tablets with or straight after a meal. **If symptoms continue, stop taking Metformin hydrochloride tablets and talk to your doctor.**

Common side effects (in less than 1 in 10 people)

- changes in taste.

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

- 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 hydrochloride tablets immediately and tell your doctor straight away.**
- 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.

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.

5. HOW TO STORE METFORMIN HYDROCHLORIDE TABLETS

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

This medicinal product does not require any special storage conditions.

Do not use Metformin hydrochloride tablets after the expiry date which is stated on the carton or the blister after 'EXP'. The expiry date refers to the last day of that month.

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 tablet contains

- The active substance is metformin hydrochloride.

Metformin hydrochloride 500 mg tablets:

Each film-coated tablet contains 500 mg metformin hydrochloride corresponding to 390 mg metformin.

Metformin hydrochloride 850 mg tablets:

Each film-coated tablet contains 850 mg metformin hydrochloride corresponding to 663 mg metformin.

Metformin hydrochloride 1000 mg tablets:

Each film-coated tablet contains 1000 mg metformin hydrochloride corresponding to 780 mg metformin.

- The other ingredients are:

Tablet core: Povidone, magnesium stearate.

Film-coating: Hypromellose, macrogol.

What Metformin hydrochloride tablets looks like and contents of the pack

Film-coated tablet.

Metformin hydrochloride 500 mg tablets:

White, round, biconvex, film-coated tablets with 'A' debossed on one side and '60' debossed on the other side.

Metformin hydrochloride 850 mg tablets:

White, round, biconvex, film-coated tablets with 'A' debossed on one side and '61' debossed on the other side.

Metformin hydrochloride 1000 mg tablets:

White, oval, biconvex, film-coated tablets with 'A' debossed on one side and '62' debossed on the other side. The tablets have a non-functional groove and therefore cannot be broken.

Metformin hydrochloride tablets are packed in a blister pack.

Metformin hydrochloride 500 mg & 850 mg tablets:

Each box contains 20/28/30/40/42/50/56/60/70/80/84/90/98/100/120/180/200/300/400 film-coated tablets in blister packs, each blister containing 10 or 14 film-coated tablets.

Metformin hydrochloride 1000 mg tablets:

Each box contains 20/30/40/50/60/70/80/90/100/120/180 film-coated tablets in blister packs, each blister containing 10 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aurobindo Pharma Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

Manufacturer

Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom
or
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg Filmtabletten
Belgium	Metformine Aurobindo 500 mg/ 1000 mg comprimés pelliculés
Bulgaria	Metformin-ratiopharm 500 mg/ 850 mg/ 1000 mg филмирани таблетки
Czech Republic	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg potahované tablety
Denmark	Metformin "Aurobindo"
Estonia	Metformin Aurobindo
Finland	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg tabletti, kalvopäällysteinen
France	METFORMINE AUROBINDO 500 mg/ 850 mg/ 1000 mg, comprimé pelliculé
Germany	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg Filmtabletten
Greece	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg επικαλυμμένο με λεπτό υμένιο δισκία
Hungary	Metformin Aurobindo 500 mg/ 850 mg filmtabletta, Adimet 1000 mg filmtabletta
Ireland	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg film-coated tablets
Italy	METFORMINA DOC Generici 500 mg/ 850 mg/ 1000 mg, compresse rivestite con film
Latvia	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg, apvalkotās tabletes
Lithuania	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg plėvele dengtos tabletės
Netherlands	Metformine HCl Aurobindo 500 mg/ 850 mg/ 1000 mg, filmomhulde tabletten
Norway	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg filmdrasjerte tablett
Poland	Metformin Aurobindo
Portugal	Metformina Aurobindo
Romania	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg comprimate filmate
Slovakia	Metformín Aurobindo 500 mg/ 850 mg/ 1000 mg filmom obalené tablety
Slovenia	Metformin Aurobindo 500 mg/ 850 mg/ 1000 mg filmsko obložene tablete
Spain	Metformina ratiopharm 500 mg/ 850 mg/ 1000 mg comprimidos recubiertos con película
Sweden	Metformin Aurobindo
United Kingdom	Metformin hydrochloride 500 mg/ 850 mg/ 1000 mg film-coated tablets

This leaflet was last approved in 08/2011.