Package leaflet: Information for the user

Metformin Hydrochloride Amarox 500mg Prolonged-release Tablets
Metformin Hydrochloride Amarox 750mg Prolonged-release Tablets
Metformin Hydrochloride Amarox 1000mg Prolonged-release Tablets

metformin hydrochloride

This medicine is intended for **adult** patients only

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 Hydrochloride Amarox is and what it is used for
2. What you need to know before you take Metformin Hydrochloride Amarox
3. How to take Metformin Hydrochloride Amarox
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1. What Metformin Hydrochloride Amarox is and what it is used for

Metformin Hydrochloride Amarox prolonged release tablets contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of Type 2 (non-insulin dependent) diabetes mellitus.

Metformin Hydrochloride Amarox is used together with diet and exercise to lower the risk of developing Type 2 diabetes in overweight adults, when diet and exercise alone for 3 to 6 months have not been enough to control blood glucose (sugar). You are at high risk of developing Type 2 diabetes if you have additional conditions like high blood pressure, age above 40 years, an abnormal amount of lipids (fat) in the blood or a history of diabetes during pregnancy.

The medicine is particularly effective if you are aged below 45 years, are very overweight, have high blood glucose levels after a meal or developed diabetes during pregnancy.

Metformin Hydrochloride Amarox is used for the treatment of Type 2 diabetes when diet and exercise changes alone have not been enough to control blood glucose (sugar). Insulin is a hormone that enables body tissues to take glucose from the blood and to use it for energy or for storage for future use. People with Type 2 diabetes do not make enough insulin in their pancreas or their body does not respond properly to the insulin it does make. This causes a build-up of glucose in the blood which can cause a number of serious long-term problems so it is important that you continue to take your medicine, even though you may not have any obvious symptoms. Metformin Hydrochloride Amarox makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Metformin Hydrochloride Amarox is associated with either a stable body weight or modest weight loss.

Metformin Hydrochloride Amarox Prolonged-Release Tablets are specially made to release the drug slowly in your body and therefore are different to many other types of tablet containing metformin.

Polycystic ovary syndrome (PCOS) is a health condition that affects a woman's hormone levels, menstrual cycle, and ability to have children. Metformin Hydrochloride Amarox is used in women

with PCOS to stimulate ovulation (release of an egg from the ovaries) and subsequently the chance of getting pregnant, alone or together with other treatment options.

2. What you need to know before you take Metformin Hydrochloride Amarox

Do not take Metformin Hydrochloride Amarox if:

- you are allergic to metformin or to any of the other ingredients of this medicine (listed in section 6). An allergic reaction may cause a rash, itching or shortness of breath.
- you have liver problems
- you have severely reduced kidney function
- 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.
- you have lost too much water from your body (dehydration). Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- 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 'Warnings and precautions').
- you have been treated for acute heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- you are a heavy drinker of alcohol.
- you are under 18 years of age.

Warnings and precautions

Risk of lactic acidosis

Metformin Hydrochloride Amarox 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.

Stop taking Metformin Hydrochloride Amarox 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 Hydrochloride Amarox 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.

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.

If you need to have major surgery you must stop taking Metformin Hydrochloride Amarox during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Metformin Hydrochloride Amarox.

During treatment with Metformin Hydrochloride Amarox, 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.

If you are older than 75 years, treatment with Metformin Hydrochloride Amarox should not be started to lower the risk of developing type 2 diabetes.

You may see some remains of the tablets in your stools. Do not worry - this is normal for this type of tablet.

You should continue to follow any dietary advice that your doctor has given you and you should make sure that you eat carbohydrates regularly throughout the day.

Do not stop taking this medicine without speaking to your doctor.

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

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 Hydrochloride Amarox. It is especially important to mention the following:
- Medicines which increase urine production (diuretics (water tablets) such as furosemide).
- 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)
- Steroids such as prednisolone, mometasone, beclometasone.
- Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure. Epinephrine is also included in some dental anaesthetics.
- Medicines that may change the amount of Metformin Hydrochloride Amarox in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).

Metformin Hydrochloride Amarox with alcohol
Avoid excessive alcohol intake while taking Metformin Hydrochloride Amarox 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.

Women of childbearing potential:
Metformin Hydrochloride Amarox can stimulate ovulation (release of an egg from the ovaries), in women who do not ovulate properly. Beware of an increased chance of becoming pregnant when using Metformin Hydrochloride Amarox.

Driving and using machines
Metformin Hydrochloride Amarox taken on its own does not cause 'hypos' (symptoms of low blood sugar or hypoglycaemia, such as faintness, confusion and increased sweating) and therefore should not affect your ability to drive or use machinery.

You should be aware, however, that Metformin Hydrochloride Amarox taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

Metformin Hydrochloride Amarox contains Sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per prolonged-release tablet, that is to say essentially 'sodium free'.

3. How to take Metformin Hydrochloride Amarox

Your doctor may prescribe Metformin Hydrochloride Amarox for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

Always take this medicine exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water, do not chew.

Recommended dose
Usually you will start treatment with 500 milligrams Metformin Hydrochloride Amarox. After you have been taking Metformin Hydrochloride Amarox for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligrams of Metformin Hydrochloride Amarox.

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

Normally, you should take the tablets once a day, with your evening meal.

In some cases, your doctor may recommend that you take the tablets twice a day. Always take the tablets with food.

Polycystic ovary syndrome (PCOS)
The usual dose is 1500-2000 mg metformin hydrochloride taken once a day with the evening meal. You should check with your doctor or pharmacist when to stop taking the medicine.

If you take more Metformin Hydrochloride Amarox than you should
If you take extra tablets by mistake you need not worry, but if you have unusual symptoms, contact your doctor. If the overdose is large, lactic acidosis is more likely. Symptoms of lactic acidosis are non-specific, such as vomiting, bellyache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heart beat. If you experience some of these symptoms, you should immediately seek medical attention, as lactic acidosis may lead to coma. Stop taking Metformin Hydrochloride Amarox immediately and contact a doctor or the nearest hospital straightaway.

If you forget to take Metformin Hydrochloride Amarox
Take it as soon as you remember with some food. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

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

Metformin Hydrochloride Amarox may cause abnormal liver function tests and hepatitis (inflammation of the liver) which may result in jaundice (may affect up to 1 in 10,000 people). If you develop yellowing of the eyes and/or skin contact your doctor immediately.

Other possible side effects are listed by frequency as follows:
Very common (may affect more than 1 in 10 people):

- Diarrhoea, nausea, vomiting, stomach ache or loss of appetite. If you get these, do not stop taking the tablets as these symptoms will normally go away in about 2 weeks. It helps if you take the tablets with or immediately after a meal.

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

- Taste disturbance
- 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 rashes including redness, itching and hives.

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: Yellow Card Scheme Website: 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 Hydrochloride Amarox

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Hydrochloride Amarox contains
Each prolonged-release tablet contains 500 mg Metformin Hydrochloride corresponding to 390 mg Metformin base.
Each prolonged-release tablet contains 750 mg Metformin Hydrochloride corresponding to 585 mg Metformin base.
Each prolonged-release tablet contains 1000 mg Metformin Hydrochloride corresponding to 780 mg Metformin base.

The other ingredients are:

Povidone, silica, colloidal anhydrous, sodium carboxymethyl cellulose, hypromellose (100000 cps), cellulose, microcrystalline, magnesium stearate.

What Metformin Hydrochloride Amarox looks like and contents of the pack.
Prolonged-release Tablet.

Metformin Hydrochloride Amarox 500mg
White to off white, round shaped, biconvex, tablets, debossed on one side with “500”and other side plain. The tablets are approximately 12.15mm in diameter.

Metformin Hydrochloride Amarox 750mg
White to off white, capsule shaped, biconvex tablets, debossed on one side with '750' and on the other side plain. The tablets are approximately 20.0 mm in length and 9.6 mm in breadth.

Metformin Hydrochloride Amarox 1000mg
White to off white, capsule shaped, biconvex tablets, debossed on one side with '1000' and on the other side plain. The tablets are approximately 22.6 mm in length and 10.6 mm in breadth.

The tablets are available in pack sizes of 28 and 56 tablets.

Not all the pack sizes may be marketed.

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This leaflet was last revised in 02/2026.