

## **Package leaflet: Information for the user**

**Xynox 500 mg Prolonged-release Tablets**  
**Xynox 750 mg Prolonged-release Tablets**  
**Xynox 1000 mg Prolonged-release Tablets**  
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 Xynox is and what it is used for
2. What you need to know before you take Xynox
3. How to take Xynox
4. Possible side effects
5. How to store Xynox
6. Contents of the pack and other information

#### **1. What Xynox is and what it is used for**

Xynox 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 diabetes (also called ‘non-insulin dependent diabetes’), when diet and exercise changes alone have not been enough to control blood glucose (sugar).

Insulin is a hormone produced by the pancreas that makes your body take in glucose (sugar) 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. Xynox makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Xynox 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 below 45 years old, are very overweight, have high blood glucose levels after a meal or developed diabetes during pregnancy.

Metformin is associated with either a stable body weight or modest weight loss. Xynox prolonged release tablets are specially made to release the medicine slowly in your body and therefore are different to many other types of tablet containing metformin.

## **2. What you need to know before you take Xynox**

### **Do not take Xynox if:**

- you are allergic to metformin or 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 lungs 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**

Talk to your doctor or pharmacist before taking Xynox.

### **Risk of lactic acidosis**

Xynox 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 part of the body has a reduced supply of oxygen (such as acute severe heart disease).

, 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 Xynox 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 Xynox 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 this medicine during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Xynox. During treatment with this medicine, 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 Xynox 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.

### **Children and adolescents**

This medicine is intended for adult patients only.

### **Other medicines and Xynox**

Tell your doctor or pharmacist 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 Xynox.

If you need to have an injection of contrast medium that contains iodine into your bloodstream, in the context of an X-ray or scan, you must stop taking Xynox before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Xynox.

It is especially important to mention to your doctor if you are taking:

- 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 in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).

### **Xynox with alcohol**

Avoid excessive alcohol intake while taking Xynox 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**

Xynox 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 Xynox taken together with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

## **3. How to take Xynox**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor may prescribe Xynox for you to take on its own, or together with other oral antidiabetic medicines or insulin.

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

### **Recommended dose**

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

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

The maximum dose is 1000 mg daily. The kidney function should be closely monitored (every 3 – 6 months).

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.

### **If you take more Xynox 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 heartbeat.

**If you experience some of these symptoms, you should immediately seek medical attention**, as lactic acidosis may lead to coma. Stop taking Xynox immediately and contact a doctor or the nearest hospital straight away.

### **If you forget to take Xynox**

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

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.

Xynox may cause a very rare (may affect up to 1 in 10,000 people) but very serious side effect called lactic acidosis (see section ‘Warnings and Precautions’), particularly if your kidneys are not working properly. If this happens, you **must stop taking Xynox and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

Xynox 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 side effects which may occur:

**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 (itchy rash).

#### 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 at [www.mhra.gov.uk/yellowcard](http://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 Xynox

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 after “EXP”. The expiry date refers to the last day of that month.

Store below 25°C in the original package

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 Xynox contains**

- The active substance is metformin hydrochloride.

One prolonged release tablet of Xynox 500 mg contains 500 mg of metformin hydrochloride corresponding to 390 mg of metformin base.

One prolonged release tablet of Xynox 750 mg contains 750 mg of metformin hydrochloride corresponding to 585 mg of metformin base.

One prolonged release tablet of Xynox 1000 mg contains 1000 mg of metformin hydrochloride corresponding to 780 mg of metformin base.

The other ingredients for 500 mg and 750 mg are: microcrystalline cellulose (E460), magnesium stearate, carmellose sodium (E466), hypromellose (E464), colloidal anhydrous silica.

The other ingredients for 1000 mg are: calcium hydrogen phosphate anhydrous (E341), carmellose sodium (E466), hypromellose (E464), povidone (E1201), colloidal anhydrous silica, magnesium stearate.

### **What Xynox looks like and contents of the pack**

Xynox 500 mg Prolonged-release Tablets: White to off white coloured, round, (12.10 mm - 12.50 mm) uncoated tablets debossed with '16' on one side and 'C' on other side.

Supplied in Aluminium Clear PVDC blister pack with pack size 28 tablets and 56 tablets.

Xynox 750 mg Prolonged-release Tablets: White to off white coloured, capsule shaped, uncoated tablets debossed with '15' on one side and 'C' on other side. The tablet dimensions are  $19.00 \pm 0.2\text{mm} \times 9.50 \pm 0.2 \text{ mm}$

Supplied in Aluminium Clear PVDC blister pack with pack size 28 tablets and 56 tablets.

Xynox 1000 mg Prolonged-release Tablets: White to off white coloured, modified capsule shaped uncoated tablets debossed with '14' on one side and 'C' on other side. The tablet dimensions are  $22.50 \text{ mm} \times 10.50 \text{ mm} \pm 0.20 \text{ mm}$ .

Supplied in Aluminium Clear PVDC blister pack with pack size 28 tablets and 56 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

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