

Package leaflet: Information for the User

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

1. WHAT YALTORMIN SR IS AND WHAT IT IS USED FOR

Yaltormin SR prolonged release tablets contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of diabetes. Yaltormin SR is used for the treatment of Type 2 (non-insulin dependent) diabetes mellitus 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. Yaltormin SR makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Yaltormin SR is associated with either a stable body weight or modest weight loss.

Yaltormin SR 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE YALTORMIN SR

Do not take Yaltormin SR if:

- you are allergic to metformin or to any of the other ingredients which are listed later on in the leaflet (see under '6. Further information'). An allergic reaction may cause a rash, itching or shortness of breath.
- you have ketosis (this is a symptom of uncontrolled diabetes in which substances called 'ketone bodies' accumulate in the blood – you may notice that your breath has an unusual, fruity odour).
- you have liver problems or kidney problems (glomerular filtration rate (GFR) below 45 ml/min).
- you have had serious complications with your diabetes or other serious conditions which resulted in rapid weight loss, nausea, vomiting or 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

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. (See below under **Other medicines and Yaltormin SR**)
- you need to have major surgery.

You must stop taking Yaltormin SR 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.

After you have started taking your medicine:

If you have diabetes you should have your blood or urine tested for sugar regularly. You should return to your doctor at least once a year to check the function of your kidneys (more often if you are elderly or if you have kidney problems).

Please note the following particular risk of lactic acidosis.

Yaltormin SR may cause a very rare, but very serious complication called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, prolonged fasting or alcohol intake, body fluid deficit (dehydration) due to severe diarrhoea or vomiting, liver problems and any medical conditions in which a region of the body is deprived with a lack of oxygen supply (such as acute severe heart diseases).

It is important to you to comply with your medication intake, dietary instructions and regular exercise program because this can reduce the risk of lactic acidosis.

The onset of lactic acidosis can be subtle and the symptoms can be non-specific such as 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 heart beat. **If you experience some of these symptoms, you should immediately seek medical attention, as lactic acidosis may lead to coma. Stop taking Yaltormin SR immediately and contact a doctor or the nearest hospital straight away.**

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 Yaltormin SR:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any 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 Yaltormin SR for a certain period of time before and after (at least 48 hours) the examination (see 'Make sure you ask your doctor for advice' above).

If you are taking any of the following medicines, your blood sugar levels may need to be checked more often and your dose adjusted:

- Steroids such as prednisolone, mometasone, beclometasone.
- Diuretics (water tablets) such as furosemide.
- Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure. Epinephrine is also included in some dental anaesthetics.

You should avoid using alcohol-containing medicines as this will increase the risk of lactic acidosis (see under '4. Possible side effects').

Yaltormin SR with food, drink and alcohol:

You should take Yaltormin SR with or immediately after food.

You should avoid drinking alcohol as this will increase the risk of lactic acidosis (see under '4. Possible side effects').

Pregnancy and breast-feeding

Do not take Yaltormin SR if you are pregnant or breast feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Yaltormin SR 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 Yaltormin SR taken 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 YALTORMIN SR

Your doctor may prescribe Yaltormin SR 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. 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 Yaltormin SR daily. After you have been taking Yaltormin SR for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligrams of Yaltormin SR.

In renal impaired patients with a GFR between 45 and 60 ml/min, the starting dose is 500 mg or 750 mg Yaltormin SR once daily. The maximum dose is 1000 mg daily. The renal 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 Yaltormin SR 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 Yaltormin SR immediately and contact a doctor or the nearest hospital straightaway.

If you forget to take Yaltormin SR

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. **If you notice any of the following, stop taking Yaltormin SR and see your doctor immediately:**

- unexpected weight loss
- very severe nausea or vomiting
- a general feeling of not being well with severe tiredness
- very fast breathing which you cannot stop
- reduced heart beat
- stomach pains with muscle cramps or feeling cold

These can be signs of serious problems with your diabetes and may mean you have a very rare side effect called "lactic acidosis" (too much acid in the blood). If this happens, see a doctor as you will need treatment straight away.

- Abnormal liver function tests and hepatitis (inflammation of the liver) which may result in jaundice. 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 (affects more than 1 person in 10):

- 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 (affects less than 1 person in 10, but more than 1 person in 100):

- Taste disturbance

Very rare (affects less than 1 person in 10,000):

- Decreased vitamin B12 levels
- 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 the national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971;

Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE YALTORMIN SR

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

Do not use them after the expiry date which is stated on the carton 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. FURTHER INFORMATION

What Yaltormin SR contains

Yaltormin SR 500mg Prolonged Release Tablets contain 500mg of the active ingredient metformin hydrochloride, equivalent to 390mg metformin.

Yaltormin SR 750mg Prolonged Release Tablets contain 750mg of the active ingredient metformin hydrochloride equivalent to 585mg metformin.

Yaltormin SR 1000mg Prolonged Release Tablets contain 1000mg of the active ingredient metformin hydrochloride equivalent to 780mg metformin.

The other ingredients are magnesium stearate, silica colloidal anhydrous, carmellose sodium and hypromellose.

What Yaltormin SR looks like and contents of the pack

The 500 milligram tablets are white to off-white, capsule shaped tablets debossed with 'SR 500' on one side and plain on other side. The tablets dimensions are approximately 16.5mm x 8.2mm.

The 750 milligram tablets are white to off-white, capsule shaped tablets debossed with 'SR 750' on one side and plain on other side. The tablets dimensions are approximately 19.6mm x 9.3mm.

The 1000 milligrams tablets are white to off-white, oval tablets debossed with 'SR 1000' on one side and plain on other side. The tablets dimensions are approximately 22mm x 10.5mm.

Yaltormin SR is supplied in packs of 28 and 56 prolonged release tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Yaltormin SR 500mg Prolonged Release Tablets	29831/0655
Yaltormin SR 750mg Prolonged Release Tablets	29831/0656
Yaltormin SR 1000mg Prolonged Release Tablets	29831/0657

This is a service provided by the Royal National Institute of Blind People.

For the Republic of Ireland please call +44 1978 669272

Useful tips

- If you smoke, try to stop
- Take regular exercise
- Drink as little alcohol as possible
- Look after your feet. Ask about this at the surgery or hospital
- Carry a card, bracelet or disk saying you are diabetic
- Visit your diabetic clinic regularly

If you want more information about diabetes contact:

Diabetes UK Central Office

Macleod House

10 Parkway

London NW1 7AA

Tel: 020 7424 1000

This leaflet was last revised in 03/2016.