

Package leaflet: Information for the user

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

1. What Bolamyn SR is and what it is used for

Bolamyn SR 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. Bolamyn SR helps to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking Bolamyn SR over a long period of time also helps to lower the risk of complications associated with diabetes. Metformin is associated with either a stable body weight or modest weight loss.

Bolamyn SR 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 Bolamyn SR on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).

2. What you need to know before you take Bolamyn SR

Do not take Bolamyn SR Tablets

- If you are allergic to metformin hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you have liver problems.

- If you have severely reduced kidney function.
- If 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.
- 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 'Warnings and precautions').
- 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 'Warnings and precautions').
- 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 in oxygen supply to tissue which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- If you drink a lot of alcohol.
- If you are a child.

If any of the above applies to you, talk to your doctor, before you start taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bolamyn SR Tablets.

Risk of lactic acidosis

Bolamyn SR 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 applies to you, talk to your doctor for further instructions.

Stop taking Bolamyn SR 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 Bolamyn SR 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 Bolamyn SR during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Bolamyn SR.

Bolamyn SR on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Bolamyn SR together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulfonylureas, insulin, meglitinides), there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia 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.

During treatment with Bolamyn SR, 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.

Children and adolescents

Children and adolescents should not take Bolamyn SR.

Other medicines and Bolamyn SR Tablets

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 Bolamyn SR before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Bolamyn SR.

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 Bolamyn SR. It is especially important to mention the following:

- medicines which increase urine production (diuretics)
- 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)
- 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).
- 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.

Bolamyn SR Tablets with alcohol

Avoid excessive alcohol intake while taking Bolamyn SR since this may increase the risk of lactic acidosis (see section 'Warnings and precautions').

Pregnancy and breast-feeding

During pregnancy, you need insulin to treat your diabetes. Tell your doctor if you are, think you might be or are planning to become pregnant, so that he or she may change your treatment.

This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machines

Bolamyn SR 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 Bolamyn SR together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulfonylureas, insulin, meglitinides). 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 Bolamyn SR

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

Bolamyn SR 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.

The recommended doses is

For patients taking Bolamyn SR by itself or combined with other oral antidiabetic medicines:

The recommended starting dose is one tablet once a day. After 10 to 15 days, your doctor will adjust the dose on the basis of blood glucose measurements. Your doctor may increase the dose up to a maximum of 2000 mg of metformin hydrochloride per day (four of these 500 mg Bolamyn SR tablets in one day).

For patients already taking metformin and switching to Bolamyn SR:

The recommended starting dose of Bolamyn SR should be equal to your daily dose of metformin immediate-release tablets.

For patients taking Bolamyn SR combined with insulin:

When taking Bolamyn SR with insulin, the recommended starting dose is one tablet once a day, while insulin dosage is adjusted on the basis of blood sugar measurements.

Monitoring

- Your doctor will perform regular blood glucose tests and will adapt your dose of Bolamyn SR to your blood glucose levels. Make sure that you talk to your doctor regularly. This is particularly important 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 Bolamyn SR

The tablets should be swallowed whole with a drink of water during or after your evening

meal.

This is a prolonged-release tablet which is a type of tablet that spreads the release of the medication over a longer period of time than an immediate release tablet. You may see the shell of the tablet in your bowel motions. This is normal. Ask your doctor or pharmacist if you need additional information.

If you take more Bolamyn SR than you should

If you have taken more Bolamyn SR than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are 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 seek immediately medical attention, as lactic acidosis may lead to coma. Stop taking Bolamyn SR immediately and contact a doctor or the nearest hospital straight away..**

If you forget to take Bolamyn SR

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.

The following side effects are very serious and if you experience those you should **seek urgent medical attention**:

Very rare (may affect up to 1 in 10,000 people)

- Bolamyn SR may cause a very rare, but very serious side effect called lactic acidosis particularly if your kidneys are not working properly. Symptoms of lactic acidosis are non-specific (see section ‘Warnings and precautions’). If this happens you must **stop taking Bolamyn SR and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.
- 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 Bolamyn SR and talk to your doctor**.

The following other side effects have been reported at the approximate frequencies shown:

Very common (may affect 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 Bolamyn SR. It helps if you take Bolamyn SR with or straight after a meal. **If symptoms continue, stop taking Bolamyn SR and talk to your doctor.**

Common (may affect up to 1 in 10 people)

- Changes in taste.

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)
- Low vitamin B₁₂ levels in the blood.

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 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 Bolamyn SR

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 blister and 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. Contents of the pack and other information

What Bolamyn SR contains

- The active substance is metformin hydrochloride. Each prolonged-release tablet contains 500 mg metformin hydrochloride equivalent to 390 mg of metformin.
- The other ingredients are hypromellose (E454), ethylcellulose, cellulose microcrystalline and magnesium stearate.

What Bolamyn SR look like and contents of the pack

- Bolamyn SR 500 mg prolonged-release tablets are white to off white, oval shaped tablets, debossed with “93” on one side and “7267” on the other side

The tablets are available in pack sizes of 1, 20, 28, 30, 56, 60, 90 & 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

TEVA UK Ltd, Eastbourne, East Sussex, BN22 9AG

Manufacturer

Pharmachemie B.V.,
Swensweg 5, PO Box, 552, 2003 RN, Haarlem, The Netherlands

Or*

TEVA Pharmaceutical Works Company Ltd

Pallagi Street 13, H-4042 Debrecen, Hungary

Or*

Teva Operations

Poland Sp. z.o.o., ul . Mogilska 80, 31-546 Kraków, Poland

** Only the actual site of batch release will appear on the printed version of the leaflet.*

This leaflet was last revised in 08/2021.

PL 00289/1013