



PACKAGE LEAFLET
INFORMATION FOR THE USER

Lucomet® SR 750 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.

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

Lucomet 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. Lucomet SR is used for the treatment of Type 2 (non-insulin dependant) 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. Lucomet SR makes the body more sensitive to insulin and helps return to normal the way your body uses glucose. Lucomet SR is associated with either a stable body weight or modest weight loss. Lucomet 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 LUCOMET SR

Do NOT take Lucomet SR if:

- you are allergic to metformin or to any of the other ingredients which are listed later on in the leaflet (see under section '6. Further information').
- 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 long-term kidney or liver problems.
- you have had serious complications with your

diabetes or other serious conditions which resulted in rapid weight loss, nausea, vomiting or dehydration.

- you have a severe infection or have recently suffered a severe injury
- you have been treated for heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties.
- you are a heavy drinker of alcohol.
- you are under 18 years of age.

Warnings and precautions

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 the 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).

If you start to lose weight unexpectedly or suffer severe nausea or vomiting, uncontrolled rapid breathing or abdominal pains, stop taking the medicine and tell your doctor straight away. This can be a sign of a rare, but serious, complication with your diabetes called 'lactic acidosis' which means there is too much acid in the blood (see also under section '4. Possible side effects').

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

If you need to have an X-ray examination involving the injection of a dye, tell the doctor that you take Lucomet SR as you may need to stop taking it for a few days afterwards. Tell your doctor if you are going to have an operation under general anaesthetic, as you may need to stop taking Lucomet SR for a couple of days before and after the procedure. 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 Lucomet SR

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

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

Lucomet SR with food and drink

You should take Lucomet SR with or immediately after food.

Pregnancy and breast-feeding

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

Driving and using machines

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

Lucomet SR contains sodium

This medicinal product contains up to 1.4 mmol (or 31.1mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE LUCOMET SR

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

Your doctor will tell you how to take the tablets. He may measure your blood sugar and adjust the dose. The maximum daily dose is 1500 milligrams of Lucomet 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. Swallow the tablets whole with a glass of water, do not chew.

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 Lucomet 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 and this is a medical emergency requiring treatment in hospital (see also under '4. Possible side effects').

If you forget to take Lucomet 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 side effects, you may need urgent medical attention. Stop taking Lucomet SR and see your doctor immediately:

- unexpected weight loss
 - very severe nausea or vomiting
 - very fast breathing which you cannot stop
 - stomach pains 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 (may affect more than 1 in 10 people):

- Nausea
- Vomiting
- Diarrhoea
- Abdominal pain (stomach pain)
- 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 disturbances.

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

- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAPharmacovigilance, 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 LUCOMET SR

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

Do not store above 30 °C.

Do not use the tablets after the expiry date that is printed on the pack. The expiry date refers to the last day of the month.

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 Lucomet SR contain:

Each prolonged-release tablet contains 750 milligrams of the active ingredient metformin hydrochloride.

The other ingredients are, carmellose sodium 2000, Hypromellose 100M, colloidal anhydrous silica and magnesium stearate.

What Lucomet SR looks like and contents of the pack:

Lucomet SR 750 mg prolonged-release tablets are white, shallow, convex-shaped, 20 x 9mm sized tablets marked "SR1" on one side.

The tablets are available in pack sizes of 28, 30, 56, 60 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Consilient Health Ltd.,
5th floor, Beaux Lane House,
Mercer Street Lower, Dublin 2, Ireland

Manufacturer

DHL Excel Supply Chain
Cherwell 1 & 2, Middleton Close,
Banbury, Oxfordshire
OX16 4RS
United Kingdom

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