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 symptoms 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 LUCOMET SR IS AND WHAT IT IS 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 Type 2 (non-insulin dependant diabetes mellitus.

Lucomet SR 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. 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 of this medicine (listed

in section 6). An allergic reaction may cause a rash, itching or shortness of breath.

• 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 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').
• 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 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').
• if you are a heavy drinker of alcohol.
• if you are under 18 years of age.

Warnings and precautions
Talk to your doctor before taking Lucomet SR.

Risk of lactic acidosis

Lucomet 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 apply to you, talk to your doctor for further instructions.

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

During treatment with Lucomet 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.

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 Lucomet SR

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, in the context of an X-ray or scan, you must stop taking Lucomet SR before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with Lucomet 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 Lucomet SR. 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 Lucomet SR in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).

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

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 medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

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.

Always take this Lucomet SR 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.

<u>Recommended dose</u>
Usually you will start treatment with 750 milligrams Lucomet SR daily. After you have been taking Lucomet SR for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 1500 milligrams of Lucomet SR.

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.

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.
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 Lucomet SR immediately and contact a doctor or the nearest hospital straightaway.

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, Lucomet SR can cause side effects, although not everybody gets them.
The following side effects may occur:

Lucomet SR 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 Lucomet SR and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

Lucomet SR may cause abnormal liver function tests and hepatitis (inflammation of the liver) which may result in jaundice (may affect up to 1 user in 10,000). 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: 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 LUCOMET SR

Keep Lucomet SR out of the sight and reach of children.
Do not store above 30°C.
Do not use this medicine after the expiry date that is printed on the pack after "EXP."
The expiry date refers to the last day of the month.

Medicines should not be disposed of 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 the tablets contain:
Each prolonged-release tablet contains 750 mg of the active ingredient metformin hydrochloride (corresponding to 585 mg of metformin).
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
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This leaflet was last revised in October 2020.