

MELIFORT EXTENDED RELEASE TABLET

Metformin Hydrochloride (500mg, 750mg, 1000mg)

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What Melifort Extended Release Tablet is used for

Melifort Extended Release Tablet contains the active ingredient metformin hydrochloride and belongs to a group of medicines called biguanides, used in the treatment of diabetes. Melifort Extended Release Tablet is used to delay the onset and treat Type 2 (non- insulin dependent) diabetes mellitus when diet and exercise changes alone have not been enough to control blood glucose (sugar).

How Melifort Extended Release Tablet works

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.

Melifort Extended Release Tablet makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Melifort Extended Release Tablet is associated with either a stable body weight or modest weight loss.

Melifort Extended Release Tablet is specially made to release the drug slowly in your body and therefore are different to many other types of tablet containing metformin.

Before you use Melifort Extended Release Tablet

- *When you must not use it*

Do not take this medicine if:

- you are allergic to metformin or any other ingredients of this medicine (listed in Product Description)
- you have lactic acidosis [too much lactic acid in the blood (see “Risk of lactic acidosis”)] 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 of acidosis may include breathing difficulties, stomach pain, muscle cramps and drowsiness (if severe).
- you have severely-reduced kidney function.
- 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.

Take special care with Melifort Extended Release Tablet 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 severely reduced kidney function).
- If you started to have breathing difficulties, stomach pain, muscle cramps, and drowsiness (if severe), 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 ‘Side effects’).

Please note the following particular risk of lactic acidosis.

Melifort Extended Release Tablet may cause a very rare, but serious complication called lactic acidosis, particularly if your kidneys are not working properly. The risk of lactic acidosis is also increased with liver failure, uncontrolled diabetes, prolonged fasting, alcohol intake and concomitant use of medicinal products that affects renal function (see under ‘Taking other medicines’). Symptoms of lactic acidosis are vomiting, stomach ache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking Melifort Extended Release Tablet immediately and contact a doctor or the nearest hospital straight away.

- *Before you start to use it*

Check with your doctor or pharmacist before taking Melifort Extended Release Tablet if you:

- need to have an X-ray examination involving the injection of a dye.
- are going to have an operation under general anaesthetic.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, or you think you may be pregnant or are planning to have a baby, as there may be changes needed in your treatment or the 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.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if you are taking:

- 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.

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

How to use Melifort Extended Release Tablet

Your doctor may prescribe Melifort Extended Release Tablet 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. You should check with your doctor or pharmacist if you are not sure. They may differ from the information contained in this leaflet. Swallow the tablets whole with a glass of water, do not chew.

- How much to use

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

- When to use it

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.

- How long to use it

The treatment duration is not limited and depends on the severity of the disease. The duration of therapy will be determined by your doctor.

Stopping treatment must be discussed with your doctor.

- If you forget to use it

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 take too much (overdose)

If you take extra tablets by mistake and if you have unusual symptoms, contact your doctor. If the overdose is severe, lactic acidosis is more likely and this is a medical emergency requiring treatment in hospital.

While you are using Melifort Extended Release Tablet

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Melifort Extended Release Tablet.

Tell your doctor immediately if you become pregnant while using this medication.

Take Melifort Extended Release Tablet only with a doctor's prescription. 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.

During treatment with Melifort Extended Release Tablet, your doctor will check your kidney function at least once a year or more.

- Things you must not do

You should avoid drinking alcohol and using alcohol-containing medicines as this will increase the risk of lactic acidosis.

- Things to be careful of

Driving and using machines

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

Side Effects

Like all medicines, Melifort Extended Release Tablet can cause side effects, although not everybody gets them.

If you notice any of the following, stop taking Melifort Extended Release Tablet 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 indicate 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.

Other possible side effects are listed by frequency as follows:

Very common side effects (may affect more than 1 in 10 people):

- Diarrhoea, nausea, vomiting, stomach ache or loss of appetite. These undesirable effects occur most frequently during initiation of therapy and resolve spontaneously in most cases.

Common side effects (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 problems.

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

- Skin rashes including redness, itching and hives.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of Melifort
Extended Release Tablet**

- Storage

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

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 that month.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Melifort Extended Release Tablet 500mg:
White to off white, round, biconvex tablet, debossed with "L" and "6" on one side and plain on other side, approximately 12.00 mm ± 0.20 mm.

Melifort Extended Release Tablet 750mg:
White to off white coloured, capsule shaped, biconvex tablets, debossed with "L" and "5" on one side and plain on other side, approximately 19.0mm x 9.25mm.

Melifort Extended Release Tablet 1000mg:
White to off white, capsule-shaped, biconvex tablet, debossed with "L" and "4" on one side and plain on other side, approximately 22.0mm x 10.5mm.

- Ingredients

- Active ingredients:

- Metformin Hydrochloride.

- Inactive ingredients:

- Microcrystalline cellulose (PH 101)
- Hypromellose K100M CR
- Hypromellose K4M CR
- Povidone K-30
- Colloidal silicon dioxide
- Magnesium stearate.

- MAL Number(s):

Melifort Extended Release Tablet 500mg:
MAL25116035ACZ
Melifort Extended Release Tablet 750mg:
MAL25116033ACZ
Melifort Extended Release Tablet 1000mg:
MAL25116034ACZ

Manufacturer

AMN Life Science Private Limited
Village Moginand Nahan Road,
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Product Registration Holder

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