

Dianorm[®] XR

Metformin Hydrochloride

Read this entire leaflet carefully before you start taking this medicine.

- 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. 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?

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1. What Dianorm[®] XR is and what it is used for

Dianorm[®] XR 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-dependent) diabetes mellitus. Dianorm[®] XR is used together with diet and exercise to lower the risk of developing Type 2 diabetes in overweight adults, when diet and exercise alone for 3 to 6 months have not been enough to control blood glucose (sugar). You are at high risk of developing Type 2 diabetes if you have additional conditions like high blood pressure, age above 40 years, and an abnormal amount of lipids (fat) in the blood or a history of diabetes during pregnancy.

The medicine is particularly effective if you are aged below 45 years, are very overweight, have high blood glucose levels after a meal or developed diabetes during pregnancy. 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 buildup 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. Dianorm[®] XR makes the body more sensitive to insulin and helps return to normal the way your body uses glucose. Dianorm[®] XR is associated with either a stable body weight or modest weight loss. Dianorm[®] XR 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 Dianorm[®] XR

Do not take Dianorm[®] XR if you:

- are allergic to metformin or to any of the other ingredients of this medicine (listed in section 6).
- have liver problems.
- have severely reduced kidney function.
- have uncontrolled diabetes, with for example severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis or ketoacidosis.
- have lost too much water from your body (dehydration).
- have a severe infection, such as an infection affecting your lung or bronchial system or your kidney.
- 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.
- are a heavy drinker of alcohol.
- are under 18 years of age.

Warnings and precautions

Risk of lactic acidosis

Dianorm[®] XR may cause a very rare, but very serious side effect called lactic acidosis, particularly if you take 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, 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 Dianorm[®] XR 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 Dianorm[®] XR 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.

If you need to have major surgery you must stop taking Dianorm[®] XR during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Dianorm[®] XR. During treatment with Dianorm[®] XR, 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.

If you are older than 75 years, treatment with Dianorm[®] XR should not be started to lower the risk of developing type 2 diabetes.

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.

Women: Do not take Dianorm[®] XR if you are pregnant or breast feeding.

Other medicines and Dianorm[®] XR:

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 Dianorm[®] XR before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with Dianorm[®] XR.

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 Dianorm[®] XR. 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 Dianorm[®] XR in your blood, especially if you

have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).

Dianorm[®] XR with drink and alcohol

Avoid excessive alcohol intake while taking Dianorm[®] XR since this may increase the risk of lactic acidosis.

Driving and using machines

Dianorm[®] XR 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 Dianorm[®] XR 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 Dianorm[®] XR

Your doctor may prescribe Dianorm[®] XR for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

Swallow the tablets whole with a glass of water, do not chew.

Recommended dose

Usually you will start treatment with 500 milligrams Dianorm[®] XR daily. After you have been taking Dianorm[®] XR for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligrams of Dianorm[®] XR. 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 Dianorm[®] XR 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, belyache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heartbeat. If you experience some of these symptoms, stop taking Dianorm[®] XR immediately and contact a doctor or the nearest hospital straightaway.

If you forget to take Dianorm[®] XR

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, Dianorm[®] XR can cause side effects, although not everybody gets them. The following side effects may occur:

Dianorm[®] XR may cause a very rare (may affect up to 1 user in 10,000) but very serious side effect called lactic acidosis.

Dianorm[®] XR 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.

5. How to store Dianorm[®] XR

Store below 30°C.

Keep in original pack in intact conditions.

6. Contents of the pack and other information

Dianorm[®] XR 500: Film coated extended release tablets: Box of 30.

Dianorm[®] XR 750: Film coated extended release tablets: Box of 30.

Dianorm[®] XR 1000: Film coated extended release tablets: Box of 30.

Composition

Dianorm[®] XR 500: Each film coated extended release tablet contains Metformin Hydrochloride 500mg.

Dianorm[®] XR 750: Each film coated extended release tablet contains Metformin Hydrochloride 750mg.

Dianorm[®] XR 1000: Each film coated extended release tablet contains Metformin Hydrochloride 1000mg.

Excipients: Hydroxypropyl methylcellulose, carboxymethyl cellulose, methacrylic acid copolymer, polyethylene glycol, povidone, magnesium stearate, titanium dioxide, talc, colloidal silicone dioxide (Dianorm[®] XR 500).

Date of revision: June 2019.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Medicament: keep out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Benta S.A.L
Dbayah - Lebanon