

# GLUCIENT XR EXTENDED-RELEASE TABLET

Metformin Hydrochloride 750 mg & 1000 mg

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## What Glucient XR Extended-release Tablet is used for

Glucient XR Extended-release Tablet contains the active ingredient metformin hydrochloride and belongs to a group of medicines called biguanides, used in the treatment of diabetes.

Glucient XR Extended-release Tablet is used to delay the onset and treat type 2 (non-insulin dependent) diabetes mellitus in adults, when diet and exercise changes alone have not been enough to control blood glucose (sugar). Glucient XR Extended-release Tablet may be used as monotherapy or in combination with other oral antidiabetic agents or with insulin.

## How Glucient XR 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. Glucient XR Extended-release Tablet makes the body more sensitive to insulin and helps return to normal the way your body uses glucose. Glucient XR Extended-release Tablet is associated with either a stable body weight or modest weight loss.

Glucient XR Extended-release Tablet is specially made to release the drug slowly in your body.

## Before you take Glucient XR Extended-release Tablet

### When you must not use it

Do not take this medicine if:

- you are allergic to metformin or to any of the other ingredients which are listed later on in the leaflet.
- you have severely reduced kidney function.
- you have lactic acidosis [too much lactic acid in the blood (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 precoma. Symptoms of acidosis may include stomach pain, abnormal breathing, and drowsiness (if severe).
- 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.

## Before you start to take it

### **Risk of lactic acidosis**

Glucient XR Extended-release Tablet 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, 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 Glucient XR Extended-release Tablet for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhea, fever, exposure to heat, or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Glucient XR Extended-release Tablet 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

Lactic acidosis is a medical emergency and must be treated in a hospital.

During treatment with Glucient XR Extended-release Tablet, your doctor will check your kidney function at least once a year or more frequently if you are elderly

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and/or if you have worsening kidney function.

- If you have severely reduced kidney function, tell the doctor that you are taking Glucient XR Extended-release Tablet as you may need to stop temporarily.
- If you have serious heart failure, tell the doctor that you are taking Glucient XR Extended-release Tablet as you may need to stop taking it.
- If you are above 75 years old, tell the doctor that you are taking Glucient XR Extended-release Tablet as it may not be helpful for your condition.
- If you are going for an imaging procedure that involves contrast media with iodine, tell the doctor that you are taking Glucient XR Extended-release Tablet as you may need to stop temporarily.
- Tell your doctor if you are going to have an operation under general anesthesia, as you may need to stop taking Glucient XR Extended-release Tablet 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 regularly throughout the day. Do not stop taking this medicine without speaking to your doctor.

If you are unsure of any situation with respect to you, please talk to a doctor or a pharmacist before you take Glucient XR Extended-release Tablet.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtain without 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 anesthetics.
- Medicines used to treat pain and inflammation (NSAIDs 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).
- Medicines that may change the amount of Glucient XR Extended-release Tablet in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).

### **How to take Glucient XR Extended-release Tablet**

Your doctor may prescribe Glucient XR Extended-release Tablet for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

Always take Glucient XR Extended-release Tablet 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.

### How much to take

Usually you will start treatment with 500mg metformin hydrochloride extended-release tablet daily. After you have been taking metformin hydrochloride extended-release tablet for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2,000 mg of Glucient XR Extended-release Tablet.

### When to take

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 take 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. Any decision to stop treatment must be discussed with your doctor.

### If you forget to take 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 you need not worry. However, if you are having unusual symptoms, contact your doctor. If it is serious overdose, lactic acidosis is more likely and this is a medical emergency requiring treatment in hospital.

### **While you are taking Glucient XR Extended-release Tablet**

#### Things you must do

Pregnancy and breastfeeding

Do not take Glucient XR Extended-release Tablet if you are pregnant or breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

#### 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

Glucient XR Extended-release Tablet taken on its own does not cause 'hypos' (symptoms of low blood sugar or hypoglycemia, such as faintness, confusion, and increased sweating) and therefore should not affect your ability to

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drive or use machinery. However, if Glucient XR Extended-release Tablet is taken with other antidiabetic medicines that can cause hypos, you should take extra care when driving or operating machinery.

### Side effects

Like all medicines, Glucient XR Extended-release Tablet can cause side effects, although not everybody gets them.

Possible side effects are listed by frequency as follows:

Very common:

- Nausea, vomiting, diarrhea, stomachache, and loss of appetite. These undesirable effects occur most frequently during the start of treatment and very likely to go away by itself. Your doctor may increase the dose slowly if you feel uncomfortable.

Common:

- Taste disturbance.

Very rare:

- The level of vitamin B<sub>12</sub> may be decreased if you have been taking metformin for long term.
- Skin discomfort such as itchiness and redness.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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](http://npra.gov.my)

[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage and Disposal of Glucient XR Extended-release Tablet

#### Storage

Keep out of reach of children.

Store at temperatures below 30°C.

Protect from light and moisture.

Do not use Glucient XR Extended-release Tablet after the expiry date which is printed on the packaging. The expiry date refers to the last day of that month.

#### Disposal

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

### Product Description

#### What it looks like?

Glucient XR 750 mg Extended-release Tablet:

White tablet, shallow convex, having dimension 20 x 9 mm, with marking "SR1" on one side and without marking on the other side.

Glucient XR 1000 mg Extended-release Tablet:

White tablet, shallow convex, having dimension 22.25 x 9 mm, with marking "SR2" on one side and without marking on the other side.

Glucient XR 750 mg Extended-release Tablet is provided in blister packs of PVC/PVDC coated RF - Alu Foil. 2 x 14 tablets in a carton.

Glucient XR 1000 mg Extended-release Tablet is provided in blister packs of PVC/PVDC coated RF - Alu Foil. 4 x 15 tablets in a carton.

#### Ingredients

Active ingredient:

Each Glucient XR 750 mg Extended-release Tablet contains 750 mg of the active ingredient metformin hydrochloride.

Each Glucient XR 1000 mg Extended-release Tablet contains 1000 mg of the active ingredient metformin hydrochloride.

Inactive ingredients:

carmellose sodium, hypromellose, colloidal anhydrous silica, magnesium stearate, purified water.

#### MAL Number:

MAL24046024ACZ (750mg)

MAL24046025ACZ (1000mg)

### Manufacturer

PT Ferron Par Pharmaceuticals  
Kawasan Industri Jababeka I  
Jl. Jababeka VI Blok J3, Cikarang  
Bekasi-Indonesia

### For

PT Dexa Medica  
Jl. Jenderal Bambang Utoyo No.  
138  
Palembang 30115-Indonesia

### Product Registration Holder

Pharmaforte (Malaysia) Sdn. Bhd.  
2, Jalan PJU 3/49,  
Sunway Damansara,  
47810 Petaling Jaya,  
Selangor Darul Ehsan, Malaysia.

### Date of revision

18 August 2025

### Serial Number

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