

Package leaflet: Information for the user

Starlix® 60 mg film-coated tablets
Starlix® 120 mg film-coated tablets
Starlix® 180 mg film-coated tablets
nateglinide

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Starlix is and what it is used for
2. What you need to know before you take Starlix
3. How to take Starlix
4. Possible side effects
5. How to store Starlix
6. Contents of the pack and other information

1. What Starlix is and what it is used for

What Starlix is

The active substance of Starlix, nateglinide, belongs to a group of medicines called oral antidiabetics.

Starlix is used to treat adult patients with type 2 diabetes. It helps to control the level of sugar in the blood. Your doctor will prescribe Starlix together with metformin, if inadequately controlled despite a maximally tolerated dose of metformin.

How Starlix works

Insulin is a substance produced in the body by the pancreas. It helps to decrease blood sugar levels, especially after meals. If you have type 2 diabetes, your body may not start producing insulin quickly enough after meals. Starlix works by stimulating the pancreas to produce insulin more quickly, which helps to keep blood sugar levels under control after meals.

Starlix tablets start to act within a very short time after they are swallowed and are eliminated from the body rapidly.

2. What you need to know before you take Starlix

Follow all instructions given to you by your doctor, pharmacist or nurse carefully, even if they are different from what is in this leaflet.

Do not take Starlix

- if you are allergic to nateglinide or any of the other ingredients of this medicine (listed in section 6).
- if you have type 1 diabetes (i.e. your body does not produce any insulin).

- if you are experiencing any symptoms of severe hyperglycaemia (very high blood sugar and/or diabetic ketoacidosis). These symptoms include excessive thirst, frequent urination, weakness, fatigue, nausea, shortness of breath or confusion.
- if you know that you have a severe liver problem.
- if you are pregnant or planning to become pregnant.
- if you are breast-feeding.

If any of these apply to you, do not take Starlix and talk to your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Starlix.

Diabetic patients may develop symptoms associated with low blood sugar (also called hypoglycaemia). Oral antidiabetics, including Starlix, may also produce symptoms of hypoglycaemia.

If you have low blood sugar you may experience sweating, tremors (feeling shaky), anxiety, difficulty concentrating, confusion, weakness or fainting or have other signs listed in section 4, "Possible side effects".

If this happens to you, eat or drink something containing sugar, and talk to your doctor.

Some people are more likely to get symptoms of low blood sugar than others. Take care:

- if you are over 65 years of age.
- if you are undernourished.
- if you have another medical condition that may cause low blood sugar (e.g. an under-active pituitary or adrenal gland).

If any of these apply to you, monitor your blood sugar levels more carefully.

Watch carefully for signs of low blood sugar, especially:

- if you have exercised more strenuously than usual.
- if you have drunk alcohol.

Talk to your doctor before taking Starlix

- if you know that you have a liver problem.
- if you have a severe kidney problem.
- if you have problems with drug metabolism.
- if you are due to have an operation.
- if you have recently suffered a fever, an accident or an infection.

Your treatment may need to be adjusted.

Children and adolescents

Starlix is not recommended for children and adolescents (under 18 years of age) because its effects in this age group have not been studied.

Elderly

Starlix can be used by people over 65 years of age. Such patients should take special care to avoid low blood sugar.

Other medicines and Starlix

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The amount of Starlix that you need may change if you take other medicines as these may cause your blood sugar levels to go up or down.

It is especially important that you tell your doctor, pharmacist or nurse if you are taking:

- Non-steroidal anti-inflammatory agents (used, for example, to treat muscle and joint pain).
- Salicylates such as aspirin (used as painkillers).
- Monoamine oxidase inhibitors (used to treat depression).
- Beta blockers or ACE inhibitors (angiotensin-converting enzyme inhibitors) (used, for example, to treat high blood pressure and certain heart conditions).
- Diuretics (used to treat high blood pressure).
- Corticosteroids such as prednisone and cortisone (used to treat inflammatory disorders).
- Inhibitors of drug metabolism such as fluconazole (used to treat fungal infection), gemfibrozil (used to treat dyslipidaemia) or sulfinpyrazone (used to treat chronic gout).
- Sympathomimetics (used, for example, to treat asthma).
- Anabolic hormones (e.g. methandrostenolone).
- St. John's Wort, also known as *Hypericum perforatum* (a herbal medicine).
- Somatropin (a growth hormone).
- Somatostatin analogues such as lanreotide and octreotide (used to treat acromegaly).
- Rifampin (used, for example, to treat tuberculosis).
- Phenytoin (used, for example, to treat seizures).

Your doctor may adjust the dose of these medicines.

Starlix with food, drink and alcohol

Take Starlix before meals (see section 3, "How to take Starlix"); its effect may be delayed if it is taken during or after meals.

Alcohol may disturb the control of your blood sugar so you are advised to talk to your doctor about drinking alcohol while taking Starlix.

Pregnancy, breast-feeding and fertility

Do not take Starlix if you are pregnant or planning to become pregnant. See your doctor as soon as possible if you become pregnant during treatment.

Do not breast-feed during treatment with Starlix.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Driving and using machines

Your ability to concentrate or react may be reduced if you have low blood sugar (hypoglycaemia). Bear this in mind if you drive a car or operate machines as you might put yourself or others at risk.

You should ask for doctor advice on driving if you have frequent episodes of hypoglycaemia or if you are not aware of the first signs of hypoglycaemia.

Starlix contains lactose

Starlix tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Starlix

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended starting dose of Starlix is 60 mg three times daily, taken before each of the three main meals. Your doctor may check the amount of Starlix that you are taking on a regular basis and may adjust the dose according to your needs. The maximum recommended dose is 180 mg three times

daily, taken before each of the three main meals.

Take Starlix before meals. Its effect may be delayed if it is taken during or after meals.

Take Starlix before the three main meals, usually:

- 1 dose before breakfast
- 1 dose before lunch
- 1 dose before dinner

It is best to take it right before a main meal but you can take it up to 30 minutes before.

Do not take it if you are not going to eat a main meal. If you miss a meal, skip that dose of Starlix and wait until your next meal.

Swallow the tablets whole with a glass of water.

Even though you are taking medicines for your diabetes, it is important to keep following the diet and/or exercise programme your doctor has recommended for you.

If you take more Starlix than you should

If you have accidentally taken too many tablets, or if someone else takes your tablets, talk to a doctor or pharmacist immediately. Medical attention may be necessary. If you experience symptoms of low blood sugar (listed in section 4, "Possible side effects"), eat or drink something containing sugar.

If you feel as if you are about to have a severe hypoglycaemic attack (which may lead to loss of consciousness or seizure), call for urgent medical help – or make sure that someone else does this for you. If you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take Starlix

If you forget to take a tablet, simply take the next one before your next meal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Starlix

Continue to take this medicine as long as your doctor prescribes it so that it can continue to control your blood sugar. Do not stop taking Starlix unless your doctor tells you to.

If you have any further questions on the use of this medicine, talk to your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects caused by Starlix are usually mild to moderate.

Common (may affect up to 1 in 10 people):

These are symptoms of low blood sugar (hypoglycaemia), which are usually mild. These include:

- sweating
- dizziness
- shaking
- weakness
- hunger
- feeling your heart beating fast
- tiredness
- feeling sick (nausea)

These symptoms can also be caused by lack of food or too high a dose of any anti-diabetic medicine you are taking. **If you do get symptoms of low blood sugar, eat or drink something containing sugar.**

Other side effects may include:

- Common (may affect up to 1 in 10 people): abdominal pain, indigestion, diarrhoea, nausea
- Uncommon (may affect up to 1 in 100 people): vomiting
- Rare (may affect up to 1 in 1,000 people): mild abnormalities in liver function tests, allergic (hypersensitivity) reactions such as rash and itching
- Very rare (may affect up to 1 in 10,000 people): skin rash with blisters affecting the lips, eyes and/or mouth, sometimes with headache, fever and/or diarrhoea

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Starlix

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in the original package.

Do not store above 30°C.

Do not use any Starlix pack that is damaged or shows signs of tampering.

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 Starlix contains

- The active substance is nateglinide. Each tablet contains 60, 120 or 180 mg nateglinide.
- The other ingredients are lactose monohydrate; cellulose, microcrystalline; povidone; croscarmellose sodium; magnesium stearate and silica, colloidal anhydrous.
- The tablet coating contains hypromellose; titanium dioxide (E171); talc; macrogol and red (60 and 180 mg tablets) or yellow (120 mg tablets) iron oxide (E172).

What Starlix looks like and contents of the pack

Starlix 60 mg film-coated tablets are pink, round tablets with “STARLIX” marked on one side and “60” on the other.

Starlix 120 mg film-coated tablets are yellow, ovaloid tablets with “STARLIX” marked on one side and “120” on the other.

Starlix 180 mg film-coated tablets are red, ovaloid tablets with “STARLIX” marked on one side and “180” on the other.

Each blister pack contains 12, 24, 30, 60, 84, 120 or 360 tablets. Not all pack sizes or tablet strengths may be available in your country.

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website:
<http://www.ema.europa.eu>