

## INFORMATION FOR THE CONSUMER

What is **Starlix\*** and what does **Starlix\*** do?

**Starlix\*** tablet contains the active substance nateglinide. **Starlix\*** tablets also contain the following non-medicinal ingredients : colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl methylcellulose, iron oxide (red or yellow), lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc and titanium dioxide.

**Starlix\*** is a medicine to lower blood sugar (glucose). **Starlix\***tablets are taken by mouth (such medicines are known as oral antidiabetics).

It is used in patients with type 2 diabetes whose condition cannot be controlled by diet and exercise alone. This kind of diabetes is also called non-insulin-dependent diabetes mellitus.

### How **Starlix** works

Insulin (produced by an organ called the pancreas) is a substance, which helps to decrease blood sugar levels, especially after meals. In patients with type 2 diabetes, the body does not respond well to insulin and may not start to make it quickly enough after meals. **Starlix\*** works by stimulating the pancreas to produce insulin more quickly and this helps to keep the blood sugar controlled after meals.

Your doctor will prescribe **Starlix\*** either by itself or together with metformin if one medicine alone is not sufficient to control your blood sugar levels. Even though you are now starting a medicine for your diabetes, it is important that you continue to follow the diet and/or exercise advised for you.

**Starlix\*** tablets start to act within a very short time after intake and are eliminated from the body rapidly.

Your doctor may check the amount of **Starlix\*** that you are taking on a regular basis. He

or she might adjust the dose according to your needs. If you have any questions about **Starlix\*** or why this medicine has been prescribed for you, ask your doctor.

### **Before you take Starlix\***

Follow all the doctor's or pharmacist instructions carefully.

### **Do not take Starlix\***

- **If you are allergic** (hypersensitive) to **Starlix\***(nateglinide) or any of the other ingredients of **Starlix\***
- **If you have** type 1 diabetes (i.e. your body does not produce any insulin)
- **If you** have diabetic ketoacidosis
- **If you** are pregnant or planning to become pregnant
- **If you** are breast-feeding
- If you are experiencing any symptoms of severe hyperglycemia (too high blood sugar and/or diabetic ketoacidosis) e.g. excessive thirst, frequent urination, weakness or fatigue, nausea, shortness of breath or confusion.
- **If you** are experiencing any symptoms of hypoglycemia, e.g. sweating, tremors (feeling shaky), anxiety, difficulty concentrating, confusion, weakness or fainting.

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

If you think you may be allergic, ask your doctor for advice.

### **Before you use Starlix\* talk to your doctor or pharmacist if you:**

If any of the following apply to you, **tell your doctor and do not take Starlix\***.

- **Have** a history of liver or kidney problems

Diabetic patients may develop symptoms associated with low blood sugar (also known as hypoglycemia). These symptoms include sweating, dizziness, shaking, weakness, hunger, palpitations (perceivable and fast heart beat), tiredness and nausea.

Oral antidiabetic drugs, including **Starlix\***, may also produce symptoms of hypoglycemia. Certain patients are more sensitive to this effect of antidiabetic treatment than others. These include patients who have exercised more strenuously than usual or drunk alcohol, who are elderly or undernourished, who are taking other oral antidiabetics, or who have another medical condition that may cause low blood sugar (e.g. an underactive pituitary or adrenal gland or kidney problems).

- If any of these conditions apply to you, talk to your doctor about it. Your blood sugar level might need to be more carefully monitored.

Your blood sugar may get too high (hyperglycemia) if you have fever, infection, surgery, or trauma (stress conditions). In such cases contact your doctor as your medication may need to be adjusted.

#### **Taking Starlix\* with food and drink**

Take **Starlix\*** before meals (see under section “When to take **Starlix\***”); its effect may be delayed if it is taken during or after meals.

Since alcohol may disturb the way **Starlix\*** works, you are advised to avoid alcohol and talk to your doctor about this.

#### **Use in the elderly**

**Starlix\*** can be used by elderly patients.

#### **Use in children and adolescents**

The use of **Starlix\*** in children has not been studied and therefore it is not recommended.

#### **Pregnancy**

- Consult your doctor as soon as possible if you become pregnant during treatment.
- Do not take **Starlix\*** if you are pregnant (see also section ‘Do not take **Starlix\***’). Your doctor will discuss with you the potential risk of taking **Starlix\*** during pregnancy.

- Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

### **Breast-feeding**

Do not breast-feed during treatment with **Starlix\***.

Ask your doctor or pharmacist for advice before taking any medicine while you are breast-feeding.

### **Driving and using machines**

All diabetic patients who drive need to be particularly careful to avoid low blood sugar. If you experience symptoms of low blood sugar you should not drive or use machines.

### **Information about some of the ingredients of Starlix\*.**

**Starlix\*** tablets contain lactose (milk sugar). If you have severe lactose intolerance, tell your doctor before taking **Starlix\***.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Other medicines may affect the actions of **Starlix\*** and, conversely, **Starlix\*** may affect the actions of other medicines. This may result in an increase or a decrease in your blood sugar levels, requiring a dose adjustment of **Starlix\***.

It is particularly important that you tell your doctor or pharmacist if you are taking any of the following:

- Nonsteroidal anti-inflammatory agents (used, for example, to treat muscle and joint pain).
- Salicylates such as aspirin (used as pain-killers).
- Monoamine oxidase inhibitors (used to treat depression).

- Beta-blockers (used, for example, to treat high blood pressure and certain heart conditions).
- Thiazides (used in the treatment of high blood pressure).
- Corticosteroids such as prednisone and cortisone (used to treat inflammatory disorders).
- Thyroid products (used to treat patients with low production of thyroid hormones).
- Sympathomimetics (used, for example, to treat asthma).
- Sulfinpyrazone (used to treat chronic gout).
- Gemfibrozil (used to lower high levels of lipids in the blood).
- Fluconazole, ketaconazole, itroconazole (used to treat fungal infections).
- anabolic hormones (used to treat anemia).
- guanethidine, gymnema sylvestre, glucomannan, thioctic acid and St John's wort (food, dietary supplements or herbal medicine).
- somatropin (a growth hormone).
- somatostatin analogues (eg. lanreotide, octreotide).
- rifampin (used, for example, to treat tuberculosis).
- Phenytoin, carbamazepine, phenobarbital (used, for example, to treat seizures-epilepsy).
- Angiotensin converting enzyme (ACE) - inhibitors (used to treat certain heart conditions)
- Oral contraceptives (used for birth control)
- Danazol (used to treat breast cysts and endometriosis)
- Cyclosporine
- Alcohol

Grapefruit juice may increase the effect of **Starlix\***. Tell your doctor if you have recently taken any of these medicines obtained without a prescription.

Your doctor may adjust the dose of these medicines.

### **How to take Starlix\***

Follow all instructions given to you by your doctor and pharmacist carefully even if they differ from the ones given in this leaflet. Do not exceed the recommended dose.

### **How much Starlix\* to take**

The usual daily dose of **Starlix\*** is 120 mg before main meals (usually breakfast, lunch and dinner). A lower dose of 60 mg may be considered if your blood sugar levels are near the normal values. The maximum recommended dose is 180 mg before main meals. Your doctor may need to adjust the dosage to your particular needs.

He/she will prescribe **Starlix\*** either by itself or together with metformin if one medicine alone is not sufficient to control your blood sugar levels.

### **How to take Starlix\***

The tablets should be swallowed whole with a glass of water.

### **When to take Starlix\***

**Starlix\*** is best taken immediately before a main meal (1 minute) but can be taken at any time in the 30 minutes before starting the meal.

If you have to skip a main meal, do not take the corresponding dose of **Starlix\***.

### **How long to take Starlix\***

Take **Starlix\*** daily before main meals as long as recommended by your doctor.

Continue taking **Starlix\*** as your doctor tells you.

If you have questions about how long to take **Starlix\***, talk to your doctor or your pharmacist.

### **If you take more Starlix\* than you should**

Seek medical advice if you have accidentally taken too many tablets. If you experience symptoms of low blood sugar – e.g. you feel dizzy, light-headed, hungry, nervous and shaky, drowsy, confused and/or sweaty – you should eat or drink something containing sugar.

Call for urgent medical assistance – or make sure that someone else does this for you - if you feel as if you are about to suffer a severe hypoglycemic episode (loss of consciousness, seizure).

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**If you forget to take Starlix\***

If you forget to take a tablet simply skip that dose and take the next one before your next meal.

Do not take a double dose of **Starlix\*** to make up for the one that you missed.

**If you stop taking Starlix\***

Do not stop taking **Starlix\*** unless your doctor tells you to. If you stop taking it, elevated blood sugar levels will no longer be controlled (see also above section “**How long to take Starlix\***”).

**Possible side effects**

The following side effects may occur during your treatment with **Starlix\***:

**Very Common**

- Hypoglycemia (low blood sugar)

If your blood sugar is low, or you experience any of the symptoms of hypoglycemia such as cold sweat, dizziness, shaking, weakness, cool pale skin, headache, rapid heart beat, feeling sick and/or difficulty in concentrating, eat a glucose tablet or high sugar drink or snack, then rest.

**Common**

- Hyperglycemia (high blood sugar)

If your blood sugar is high or you experience any of the symptoms of hyperglycemia such as increased urination, feeling thirsty, dry skin and dry mouth, talk to your doctor,

- Visual disorder
- Abdominal pain

- Nausea
- Vomiting
- Constipation

#### **Uncommon**

- Liver dysfunction
- Allergy
- Itching

If you experience any of these symptoms **talk to your doctor.**

#### **Serious Side Effects**

Sudden severe headache or worsening of headache, dizziness, fatigue or increased sweating. If you experience any of these side effects, stop taking **Starlix\*** and talk to your doctor.

*This is not a complete list of side effects. For any unexpected effects while taking **Starlix\***, contact your doctor or pharmacist.*

#### **REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to:

Canada Vigilance Program  
Health Canada  
Postal Locator 0701C  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

#### **Storing Starlix\***

Keep out of the reach and sight of children.

Store in the original package.

Store between 15-30°C.

Do not use **Starlix\*** after the expiry date shown on the box.

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

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\*Starlix\* is a registered trademark.