European Medicines Agency

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# EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

## STARLIX

## EPAR summary for the public

*This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.*
*If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).*



### What is Starlix?
Starlix is a medicine containing the active substance nateglinide. It is available as pink, round (60 mg), yellow, oval (120 mg) and red, oval (180 mg) tablets.

### What is Starlix used for?
Starlix is used in patients who have non insulin-dependent diabetes (type 2 diabetes). Starlix is used together with metformin (another antidiabetes medicine) to lower blood glucose (sugar) in patients whose diabetes cannot be controlled by metformin alone.

### How is Starlix used?
Starlix is given within one to 30 minutes before breakfast, lunch and dinner and the dose is adjusted to give the best control. A doctor should regularly test the patient's blood glucose to find the lowest effective dose. The recommended starting dose is 60 mg three times a day before meals. This dose may need to be increased to a daily dose of 120 mg three times a day after one or two weeks. The maximum total daily dose is 180 mg three times a day.

### How does Starlix work?
Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood. Nateglinide, the active ingredient in Starlix, stimulates the pancreas to produce insulin more quickly. This helps to keep the blood glucose controlled after meals and is used to control type 2 diabetes.

### How has Starlix been studied?
A total of 2,122 patients received Starlix in all trials combined. The main studies compared Starlix to placebo (a dummy treatment), or to other medicines used in type 2 diabetes (metformin, glibenclamide or troglitazone). Other studies also looked at ‘switching’ from an antidiabetes medicine to Starlix, and ‘adding’ Starlix to other antidiabetes medicines. The studies measured the level of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled. Most of the patients received treatment for up to six months: 789 received it for at least six months, and 190 received it for a year.

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**What benefit has Starlix shown during the studies?**
On its own, Starlix was shown to be more effective than placebo, but less effective than some antidiabetes medicines such as metformin. In combination with metformin, which mainly affected fasting plasma glucose (the amount of glucose in the blood when the person has not eaten anything), the effect of Starlix on HbA1c was better than either medicine alone.

**What is the risk associated with Starlix?**
Starlix may in some cases cause hypoglycaemia (low blood glucose). Other common side effects (seen in between 1 and 10 patients in 100) are abdominal (tummy) pain, diarrhoea, dyspepsia (heartburn), and nausea (feeling sick). For the full list of all side effects reported with Starlix, see the Package Leaflet.
Starlix should not be used in people who may be hypersensitive (allergic) to nateglinide or any of the other ingredients, who have type 1 diabetes or a severe liver problem, or who have diabetic ketoacidosis (a serious complication of diabetes). Its use is not recommended in pregnancy or while breast feeding. Starlix doses might also need to be adjusted when given with some medicines used in heart conditions, to treat pain, to treat asthma, and other conditions. The full list is available in the Package Leaflet.

**Why has Starlix been approved?**
The Committee for Medicinal products for Human Use (CHMP) decided that Starlix's benefits are greater than its risks for the treatment of type 2 diabetes, in combination with metformin, in patients who are not controlled despite receiving the maximum daily dose of metformin. The Committee recommended that Starlix be given marketing authorisation.

**Other information about Starlix:**
The European Commission granted a marketing authorisation valid throughout the European Union for Starlix to Novartis Europharm Limited on 3 April 2001. The marketing authorisation was renewed on 3 April 2006.

The full EPAR for Starlix is available here.

**This summary was last updated in 08-2007.**