

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

ACTOS

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 Actos?

Actos is a medicine containing the active substance pioglitazone. The white, round tablets contain 15, 30 or 45 mg of pioglitazone.

What is Actos used for?

Actos is used to treat type 2 diabetes (also known as non insulin-dependent diabetes).

- It can be used on its own (monotherapy) in patients (particularly those who are overweight) who cannot use metformin (an antidiabetic medicine).
- It can be used together with one other antidiabetic medicine (dual therapy). It can be added to metformin in patients (particularly those who are overweight) who are not satisfactorily controlled on metformin used on its own and at the maximum tolerated dose. Alternatively, it can be added to a sulphonylurea (another antidiabetic medicine) in patients for whom metformin is not suitable and who are not satisfactorily controlled with the sulphonylurea used on its own at the maximum tolerated dose.
- It can be used together with two other antidiabetic medicines, metformin and a sulphonylurea, as triple therapy in patients (particularly those who are overweight) who are not satisfactorily controlled with these two medicines.
- It can be used together with insulin in patients who are not satisfactorily controlled with insulin alone and cannot take metformin.

How is Actos used?

Actos is taken once daily with or without food. The dose is adjusted to give the best control. The recommended starting dose is 15 mg or 30 mg once daily. This dose may need to be increased after one or two weeks to up to 45 mg once daily. In combination with metformin, the current metformin dose can be continued when starting Actos treatment. In combination with a sulphonylurea or insulin, the current sulphonylurea or insulin dose can be continued when starting Actos treatment unless the patient has hypoglycaemia (low blood glucose), when the dose of the sulphonylurea or insulin should be decreased.

How does Actos 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. Pioglitazone, the active ingredient in Actos, makes the cells more sensitive to

insulin, which means that the body makes better use of the insulin it produces, the blood glucose is reduced and this helps to control type 2 diabetes.

How has Actos been studied?

Actos has been studied in clinical pharmacology studies and in clinical trials. Almost 7,000 patients received Actos in all trials combined. The studies compared Actos to placebo (a dummy treatment), or to other antidiabetic medicines (metformin, gliclazide). Some studies also looked at combining Actos with other antidiabetic medicines (sulphonylureas, insulin, metformin). Further studies also looked at long-term use of Actos. In triple therapy, the effectiveness of Actos was studied in more than 1,400 patients who were receiving a combination of metformin and a sulphonylurea, to which was added either Actos or placebo for up to 3.5 years.

The studies measured the level in the blood of a substance (glycosylated haemoglobin, HbA1c), which gives an indication of how well the blood glucose is controlled.

What benefit has Actos shown during the studies?

Actos led to a decrease in the level of HbA1c, indicating that blood glucose levels had been reduced at doses of 15 mg, 30 mg and 45 mg. Doses below 15 mg were not effective, and doses above 45 mg (once daily) did not show additional benefit. Actos on its own was shown to be as effective as metformin and gliclazide. In combination, Actos showed that it improves the control obtained in type 2 diabetes when added to existing treatment. At the end of the triple therapy study, the effect of adding Actos to the existing treatment with metformin and a sulphonylurea was a 0.94% reduction in HbA1c levels, while adding placebo led to a 0.35% reduction. In a small study examining the combination of Actos and insulin in 289 patients, patients adding Actos to insulin had a 0.69% reduction in HbA1c levels after 6 months, compared to 0.14% in those adding placebo.

What is the risk associated with Actos?

The most common side effects with Actos are visual disturbance, upper respiratory tract infection (colds), weight increase, and hypoaesthesia (decreased sensitivity to a stimulus). For the full list of all side effects reported with Actos, see the Package Leaflet.

Actos should not be used in people who may be hypersensitive (allergic) to pioglitazone or any of the other ingredients, or in patients with liver problems, heart failure or diabetic ketoacidosis (high levels of ketones [acids] in the blood).

Why has Actos been approved?

The Committee for Medicinal products for Human Use (CHMP) decided that Actos's benefits are greater than its risks for the treatment of type 2 diabetes. The committee recommended that Actos be given marketing authorisation. In monotherapy (used on its own), the committee decided that Actos should be an alternative to the standard treatment, metformin, to be used when patients cannot take metformin.

Other information about Actos:

The European Commission granted a marketing authorisation valid throughout the European Union, for Actos to Takeda Europe R & D Centre Limited on 13 October 2000. The marketing authorisation was renewed on 13 October 2005.

The full EPAR for Actos is available [here](#)

This summary was last updated in 01-2007.