



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EPAR summary for the public

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# Actos

## pioglitazone

This is a summary of the European public assessment report (EPAR) for Actos. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Actos.

### What is Actos?

Actos is a medicine that contains the active substance pioglitazone. It is available as tablets (15, 30 and 45 mg).

### What is Actos used for?

Actos is used to treat type 2 diabetes in adults (aged 18 years or over), particularly those who are overweight. It is used in addition to diet and exercise as follows:

- on its own in patients for whom metformin (another diabetes medicine) is not suitable;
- in combination with metformin in patients who are not satisfactorily controlled on metformin alone, or with a sulphonylurea (another type of diabetes medicine) when metformin is not suitable in patients who are not satisfactorily controlled on a sulphonylurea alone;
- together with both metformin and a sulphonylurea in patients who are not satisfactorily controlled despite treatment with two medicines by mouth;
- together with insulin in patients who are not satisfactorily controlled with insulin alone and cannot take metformin.

The medicine can only be obtained with a prescription.



## **How is Actos used?**

The recommended starting dose of Actos is 15 or 30 mg once a day. This dose may need to be increased after one or two weeks to up to 45 mg once a day if better blood glucose (sugar) control is needed. The tablets should be swallowed with water.

Treatment with Actos should be reviewed after three to six months, and discontinued in patients who are not deriving sufficient benefit. At subsequent reviews prescribers should confirm that benefits to patients are maintained.

## **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 or when the body is unable to use insulin effectively. The active substance in Actos, pioglitazone, makes cells (fat, muscle and liver) more sensitive to insulin, which means that the body makes better use of the insulin it produces. As a consequence, the blood glucose levels are reduced and this helps to control type 2 diabetes.

## **How has Actos been studied?**

Actos has been compared with placebo (a dummy treatment), metformin and gliclazide (a sulphonylurea) in a number of studies. Some studies also looked at combining Actos with a sulphonylurea, insulin or metformin, or with the combination of metformin and a sulphonylurea. Further studies also looked at long-term use of Actos. Almost 7,000 patients received Actos in all of the studies combined. 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.

## **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, 30 and 45 mg. Actos on its own was shown to be as effective as metformin and gliclazide. Actos also improved the glucose control obtained in type 2 diabetes when it was added to existing treatment with a sulphonylurea, insulin or metformin, or the combination of metformin and a sulphonylurea.

## **What is the risk associated with Actos?**

The most common side effects with Actos (seen in between 1 and 10 patients in 100) are upper respiratory tract infection (colds), hypoaesthesia (reduced sense of touch), visual disturbance, bone fractures and increased weight. If Actos is used in combination with other diabetes medicines, other side effects may occur. For the full list of all side effects reported with Actos, see the package leaflet.

Actos must not be used in patients who have problems with their liver, patients who have had heart failure (when the heart does not work as well as it should) or patients with diabetic ketoacidosis (a complication of diabetes). It must also not be used in patients who have or have had bladder cancer or those with blood in the urine that has not yet been investigated. For the full list of restrictions, see the package leaflet.

## **Why has Actos been approved?**

The CHMP decided that Actos's benefits are greater than its risks and recommended that it be given marketing authorisation.

## **What measures are being taken to ensure the safe and effective use of Actos?**

The company that markets Actos will produce educational material for doctors prescribing the medicine, which will cover the possible risk of heart failure and bladder cancer with treatments that contain pioglitazone, the criteria for selecting patients and the need to review treatment regularly and stop treatment if patients are no longer benefiting.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Actos have also been included in the summary of product characteristics and the package leaflet.

## **Other information about Actos:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Actos on 13 October 2000.

The full EPAR for Actos can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_Public\\_Assessment\\_Reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports). For more information about treatment with Actos, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2016.