EMA/734871/2016
EMEA/H/C/002324

EPAR summary for the public

Pioglitazone Actavis

Pioglitazone

This is a summary of the European public assessment report (EPAR) for Pioglitazone Actavis. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Pioglitazone Actavis.

For practical information about using Pioglitazone Actavis, patients should read the package leaflet or contact their doctor or pharmacist.

What is Pioglitazone Actavis and what is it used for?

Pioglitazone Actavis 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.

Pioglitazone Actavis is a 'generic medicine'. This means that Pioglitazone Actavis is similar to a 'reference medicine' already authorised in the European Union (EU) called Actos. For more information on generic medicines, see the question-and-answer document here.

Pioglitazone Actavis contains the active substance pioglitazone.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

How is Pioglitazone Actavis used?

Pioglitazone Actavis can only be obtained with a prescription.

The medicine is available as tablets (15, 30 and 45 mg) and the recommended starting dose 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.

Treatment with Pioglitazone Actavis 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 Pioglitazone Actavis 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 Pioglitazone Actavis, 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 Pioglitazone Actavis been studied?

Because Pioglitazone Actavis is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Actos. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Pioglitazone Actavis?

Because Pioglitazone Actavis is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Pioglitazone Actavis approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Pioglitazone Actavis has been shown to have comparable quality and to be bioequivalent to Actos. Therefore, the CHMP's view was that, as for Actos, the benefit outweighs the identified risk. The Committee recommended that Pioglitazone Actavis be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Pioglitazone Actavis?

The company that markets Pioglitazone Actavis 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 Pioglitazone Actavis have also been included in the summary of product characteristics and the package leaflet.

Other information about Pioglitazone Actavis

The European Commission granted a marketing authorisation valid throughout the European Union for Pioglitazone Actavis on 15 March 2012.

The full EPAR for Pioglitazone Actavis can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Pioglitazone Actavis, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 11-2016.