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EPAR summary for the public

Glidipion

Pioglitazone

This is a summary of the European public assessment report (EPAR) for Glidipion. 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 Glidipion.

What is Glidipion?

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

Glidipion is a 'generic medicine'. This means that Glidipion 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.

What is Glidipion used for?

Glidipion 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.

Glidipion is used on its own in patients for whom metformin (another antidiabetes medicine) is not suitable.

Glidipion can also be used in combination with metformin in patients who are not satisfactorily controlled on metformin alone, or with a sulphonylurea (another type of antidiabetes medicine) when metformin is not suitable ('dual therapy').

Glidipion can also be used together with both metformin and a sulphonylurea in patients who are not satisfactorily controlled despite dual therapy by mouth ('triple therapy').

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Glidipion can also be used 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 Glidipion used?

The recommended starting dose of Glidipion 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. Glidipion should not be used in patients on dialysis (a blood clearance technique used in people with kidney disease).

Treatment with Glidipion 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 Glidipion 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 Glidipion, 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 Glidipion been studied?

Because Glidipion 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 is the risk associated with Glidipion?

Because Glidipion 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 has Glidipion been approved?

The CHMP concluded that, in accordance with EU requirements, Glidipion has been shown to have comparable quality and to be bioequivalent to Actos. Therefore, the CHMP's view was that, as for Actos, the benefits outweigh the identified risks. The Committee recommended that Glidipion be given marketing authorisation.

Other information about Glidipion

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

The full EPAR for Glidipion 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 Glidipion, 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 08-2012.