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EPAR summary for the public

Enyglid

repaglinide

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

What is Enyglid?

Enyglid is a diabetes medicine that contains the active substance repaglinide. It is available as tablets (0.5, 1 and 2 mg).

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

What is Enyglid used for?

Enyglid is used in adults who have type 2 diabetes. It is used together with diet and exercise to lower blood glucose (sugar) levels in patients whose hyperglycaemia (high blood glucose levels) is not adequately controlled by diet, weight reduction and exercise. Enyglid may also be used with metformin (another diabetes medicine) in type 2 diabetes patients whose blood glucose levels are not satisfactorily controlled on metformin alone.

The medicine can only be obtained with a prescription.

How is Enyglid used?

Enyglid is taken before meals, normally up to 15 minutes before each main meal. 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. Enyglid can also be used for type 2 diabetes patients whose blood glucose levels are usually controlled well on diet, but are experiencing temporary loss of blood glucose control.

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

The recommended starting dose is 0.5 mg. This dose may need to be increased after one or two weeks.

If patients are transferred from another diabetes medicine, the recommended starting dose is 1 mg.

How does Enyglid 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. Enyglid helps the pancreas to produce more insulin at mealtimes and is used to control type 2 diabetes.

How has Enyglid been studied?

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

What are the benefits and risks of Enyglid?

Because Enyglid is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicine's.

Why has Enyglid been approved?

The CHMP concluded that, in accordance with EU requirements, Enyglid has been shown to have comparable quality and to be bioequivalent to NovoNorm. Therefore, the CHMP's view was that, as for NovoNorm, the benefit outweighs the identified risk. The Committee recommended that Enyglid be given marketing authorisation.

Other information about Enyglid

The European Commission granted a marketing authorisation valid throughout the European Union for Enyglid on 14 October 2009.

The full EPAR for Enyglid 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 Enyglid, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2014.