European Medicines Agency

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Repaglinide Teva
repaglinide

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 Repaglinide Teva?
Repaglinide Teva is a medicine that contains the active substance repaglinide. It is available as round tablets (blue: 0.5 mg; yellow: 1 mg; peach: 2 mg).
Repaglinide Teva is a 'generic medicine'. This means that Repaglinide Teva 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 Repaglinide Teva used for?
Repaglinide Teva is used in patients who have type 2 diabetes (non-insulin-dependent diabetes). It is used together with diet and exercise to lower blood glucose (sugar) levels in patients whose hyperglycaemia (high blood glucose levels) cannot be controlled by diet, weight reduction and exercise. Repaglinide Teva may also be used with metformin (another anti-diabetes medicine) in type 2 diabetes patients whose blood glucose levels are not satisfactorily controlled on metformin alone.

How is Repaglinide Teva used?
Repaglinide Teva 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. Repaglinide Teva 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.
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 anti-diabetes medicine, the recommended starting dose is 1 mg.

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

How has Repaglinide Teva been studied?
Because Repaglinide Teva is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine (this means that the two medicines produce the same levels of the active substance in the body).

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What are the benefit and risk of Repaglinide Teva?
Because Repaglinide Teva is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Repaglinide Teva been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Repaglinide Teva 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 Repaglinide Teva be given marketing authorisation.

Other information about Repaglinide Teva:
The European Commission granted a marketing authorisation valid throughout the European Union for Repaglinide Teva to Teva Pharma B.V. on 29 June 2009.

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

This summary was last updated in 06-2009.