European Medicines Agency

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Repaglinide Krka
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 for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Repaglinide Krka?
Repaglinide Krka is a medicine that contains the active substance repaglinide. It is available as round tablets (white: 0.5 mg; yellow: 1 mg; pink: 2 mg).
Repaglinide Krka is a 'generic medicine'. This means that Repaglinide Krka 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 Krka used for?
Repaglinide Krka 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.
The medicine can only be obtained with a prescription.

How is Repaglinide Krka used?
Repaglinide Krka 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 Krka 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.
Repaglinide Krka is not recommended for patients below 18 years of age because of a lack of information on safety and effectiveness in this age group.

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

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How has Repaglinide Krka been studied?
Because Repaglinide Krka is a generic medicine, studies 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 benefit and risk of Repaglinide Krka?
Because Repaglinide Krka 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.

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

Other information about Repaglinide Krka:
The European Commission granted a marketing authorisation valid throughout the European Union for Repaglinide Krka to Krka, d.d., Novo mesto on 4 November 2009.

The full EPAR for Repaglinide Krka 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 11-2009.