LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Liglinra

(linagliptin)

SE/H/2052/01/DC

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Summary Public Assessment Report

Liglinra
linagliptin

Film-coated tablet, 5 mg

This is a summary of the public assessment report (PAR) for Liglinra. It explains how Liglinra was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Liglinra.

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

What is Liglinra and what is it used for?

Liglinra is a 'generic medicine'. This means that Liglinra is similar to a 'reference medicine' already authorised in the European Union (EU) called Trajenta.

Liglinra is used for 'type 2 diabetes' in adults, if the disease cannot be adequately controlled with one oral anti-diabetic medicine (metformin or sulphonylureas) or diet and exercise alone. Liglinra may be used together with other anti-diabetic medicines e.g. metformin, sulphonylureas (e.g. glimepiride, glipizide), empagliflozin, or insulin.

How does Liglinra work?

Liglinra contains the active substance linagliptin, which belongs to a group of medicines called "oral anti-diabetics". Oral anti-diabetics are used to treat high blood sugar levels. They work by helping the body reduce the level of sugar in your blood.

How is Liglinra used?

The pharmaceutical form of Liglinra is film-coated tablets for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Liglinra have been shown in studies?

Because Liglinra is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Trajenta.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Liglinra?

Because Liglinra is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Liglinra approved?

It was concluded that, in accordance with EU requirements, Liglinra has been shown to have comparable quality and to be bioequivalent to the reference medicine Trajenta. Therefore, the Medical Products Agency in Sweden decided that, as for Trajenta, the benefits are greater than its risks and recommended that it can be approved for use.

Liglinra has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Liglinra?”

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

A risk management plan has been developed to ensure that Liglinra is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Liglinra, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

There is also an obligation to conduct measures after approval of Liglinra. The follow-up questionnaires regarding safety concerns requires alignment with the reference product Trajenta. This is required as soon as the questionnaires for Trajenta are available.

Other information about Liglinra

The full PAR for Liglinra can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Liglinra, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2021-06.