LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Sitagliptin Laurus
(sitagliptin hydrochloride monohydrate)

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Sitagliptin Laurus
sitagliptin hydrochloride monohydrate

Film-coated tablet, 25 mg, 50 mg, 100 mg

This is a summary of the public assessment report (PAR) for Sitagliptin Laurus. It explains how Sitagliptin Laurus 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 Sitagliptin Laurus.

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

What is Sitagliptin Laurus and what is it used for?

Sitagliptin Laurus is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Januvia.

Sitagliptin Laurus can be used by patients who have diabetes typ 2. This medicine helps to increase the levels of insulin produced after a meal and decreases the amount of sugar made by the body.

How does Sitagliptin Laurus work?

Sitagliptin Laurus contains the active substance sitagliptin which is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

This medicine can be used alone or in combination with certain other medicines (insulin, metformin, sulphonylureas, or glitazones) that lower blood sugar, which you may already be taking for your diabetes together with a food and exercise plan.

How is Sitagliptin Laurus used?

The pharmaceutical form of Sitagliptin Laurus is a film-coated tablet 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 Sitagliptin Laurus have been shown in studies?

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

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

What are the possible side effects from Sitagliptin Laurus?

Because Sitagliptin Laurus 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 side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Sitagliptin Laurus approved?

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

What measures are being taken to ensure the safe and effective use of Sitagliptin Laurus?
A risk management plan has been developed to ensure that Sitagliptin Laurus 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 Sitagliptin Laurus, 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.

Other information about Sitagliptin Laurus

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

This summary was last updated in 2023-01.