LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Jidinum
(sitagliptin hydrochloride monohydrate)

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Summary Public Assessment Report

Jidinum
sitagliptin, sitagliptin hydrochloride monohydrate

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

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

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

What is Jidinum and what is it used for?

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

This medicine is used to lower 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.

How does Jidinum work?

Jidinum 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 helps to increase the levels of insulin produced after a meal and decreases the amount of sugar made by the body.

How is Jidinum used?

The pharmaceutical form of Jidinum is 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 Jidinum have been shown in studies?

No additional studies were needed as Jidinum is a generic medicine considered to be 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 Jidinum?

Because Jidinum 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 Jidinum approved?

It was concluded that, in accordance with EU requirements, Jidinum 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 Jidinum?

A risk management plan has been developed to ensure that Jidinum 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 Jidinum, 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 Jidinum

The full PAR for Jidinum can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Jidinum

This summary was last updated in 2022-02.