

Summary Public Assessment Report

Sitagliptin/Metformin Grindeks (sitagliptin hydrochloride monohydrate, metformin hydrochloride)

SE/H/2115/01-02/DC

Summary Public Assessment Report

Sitagliptin/Metformin Grindeks

sitagliptin hydrochloride monohydrate, metformin hydrochloride

Film-coated tablet, 50 mg/850 mg, 50 mg/1000 mg

This is a summary of the public assessment report (PAR) for Sitagliptin/Metformin Grindeks. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Sitagliptin/Metformin Grindeks and what is it used for?

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

The product is used in the treatment of adult patients with type 2 diabetes mellitus.

How does Sitagliptin/Metformin Grindeks work?

Sitagliptin/Metformin Grindeks contains two different medicines called sitagliptin and metformin.

- sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors)
- metformin belongs to a class of medicines called biguanides.

They work together to control blood sugar levels in adult patients with a form of diabetes called 'type 2 diabetes mellitus'. This medicine helps to increase the levels of insulin produced after a meal and lowers the amount of sugar made by the body.

Along with diet and exercise, this medicine helps lower the blood sugar. This medicine can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas or glitazones).

How is Sitagliptin/Metformin Grindeks used?

The pharmaceutical form 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 Sitagliptin/Metformin Grindeks have been shown in studies?

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

What are the possible side effects from Sitagliptin/Metformin Grindeks?

Because the product 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/Metformin Grindeks approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Janumet. Therefore, the Swedish Medical Products Agency decided that, as for Janumet, 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/Metformin Grindeks?

A risk management plan has been developed to ensure that the product 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, 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/Metformin Grindeks

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

This summary was last updated in 2022-09.