LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Sitagliptin Grindeks
(sitagliptin hydrochloride monohydrate)

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Sitagliptin Grindeks
sitagliptin hydrochloride monohydrate

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

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

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

What is Sitagliptin Grindeks and what is it used for?
Sitagliptin Grindeks is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Januvia.

Sitagliptin Grindeks is used in patients with type-2 diabetes to improve the control of blood glucose (sugar) levels. It is used in addition to diet and exercise in the following ways:

- on its own, in patients who are not satisfactorily controlled on diet and exercise and in whom metformin (another antidiabetes medicine) is not suitable;
- in combination with metformin or a PPAR-gamma agonist (a type of antidiabetes medicine) such as a thiazolidinedione, in patients who are not satisfactorily controlled on metformin or the PPAR-gamma agonist used on its own;
- in combination with a sulphonylurea (another type of antidiabetes medicine) in patients who are not satisfactorily controlled with a sulphonylurea used on its own and in whom metformin is not suitable;
- in combination with both metformin, and a sulphonylurea or a PPAR-gamma agonist, in patients who are not satisfactorily controlled on the two medicines;
- in combination with insulin, with or without metformin, in patients who are not satisfactorily controlled on a stable dose of insulin.

How does Sitagliptin Grindeks work?

Type-2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose (sugar) in the blood or when the body is unable to use insulin effectively. Sitagliptin Grindeks contains the active substance sitagliptin, which is a dipeptidyl-peptidase-4 (DPP-4) inhibitor. It works by blocking the breakdown of 'incretin' hormones in the body. These hormones are released after a meal and stimulate the pancreas to produce more insulin. By increasing levels of incretin hormones in the blood, sitagliptin stimulates the pancreas to produce more insulin when blood glucose levels are high. This will help to lower the blood glucose level. Incretin hormones only stimulate insulin production when glucose levels are high. This means that sitagliptin does not lower the blood glucose level further if it is already low. Sitagliptin also reduces the amount of glucose made by the liver, by increasing insulin levels and decreasing the levels of the hormone glucagon. Together, these processes reduce blood glucose levels and help to control type-2 diabetes.

How is Sitagliptin Grindeks used?

The pharmaceutical form of Sitagliptin Grindeks 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 Sitagliptin Grindeks have been shown in studies?

Because Sitagliptin Grindeks 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 Grindeks?

Because Sitagliptin Grindeks 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 Grindeks approved?

It was concluded that, in accordance with EU requirements, Sitagliptin Grindeks 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 Grindeks?

A risk management plan has been developed to ensure that Sitagliptin Grindeks 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 Grindeks, 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 Grindeks

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

This summary was last updated in 2022-01.