Summary Public Assessment Report

Generics

Sitagliptin IASIS
Sitagliptin

SK/H/0299/001/DC

Date: March 2025

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Sitagliptin hydrochloride monohydrate, oral solution, 25 mg/mL

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

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

What is Sitagliptin IASIS and what is it used for?

Sitagliptin IASIS is a 'generic medicine'. This means that Sitagliptin IASIS is similar to a 'reference medicine' already authorised in the European Union (EU) called Januvia.
Sitagliptin IASIS is used in the treatment of type 2 diabetes. 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 does Sitagliptin IASIS work?

Sitagliptin 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.

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation.

How is Sitagliptin IASIS used?

The pharmaceutical form of Sitagliptin IASIS is oral solution and the route of administration is oral.

The usual recommended dose is 100 mg (4 ml of oral solution) once a day taken by mouth. For administration of Sitagliptin IASIS an oral syringe is packed with medicinal product to deliver patient´s specific dose.

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

The medicine can only be obtained with a prescription.

What benefits of Sitagliptin IASIS have been shown in studies?

Because Sitagliptin IASIS 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 of Sitagliptin IASIS?

Because Sitagliptin IASIS is a generic medicine and is bioequivalent to the reference 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 Sitagliptin IASIS approved?

It was concluded that, in accordance with EU requirements, Sitagliptin IASIS has been shown to have comparable quality and to be bioequivalent to reference medicine. Therefore, the State Institute for Drug Control decided that, as for the reference medicine called Januvia, the benefits are greater than its risk and recommended that it can be approved for use.

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

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

The marketing authorisation for Sitagliptin IASIS was granted on 16 December 2024.

The full PAR for Sitagliptin IASIS can be found on the website. For more information about treatment with Sitagliptin IASIS, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in 03-2025.