Summary Public Assessment Report

Generics

Sitagliptin HCS 25 mg film-coated tablets
Sitagliptin HCS 50 mg film-coated tablets
Sitagliptin HCS 100 mg film-coated tablets
Sitagliptin

SK/H/0277/001-003/DC

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(hereinafter Sitagliptin HCS)

Sitagliptin, film-coated tablets, 25 mg, 50 mg, 100 mg

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

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

What is Sitagliptin HCS and what is it used for?

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

Sitagliptin HCS 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 (an antidiabetic medicine) is not suitable.
- in combination with metformin or a PPAR-gamma agonist (a type of antidiabetic 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 antidiabetic 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 HCS work?

Type-2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. The active substance in Sitagliptin HCS, sitagliptin, 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 insulin. By increasing levels of incretin hormones in the blood, sitagliptin stimulates the pancreas to produce more insulin when blood glucose levels are high. Sitagliptin does not work when the blood glucose is 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 HCS used?

The pharmaceutical form of Sitagliptin HCS is film-coated tablet and the route of administration is oral.

Sitagliptin HCS is taken at a dose of 100 mg once a day. If Sitagliptin HCS is taken with a sulphonylurea or insulin, the dose of the sulphonylurea or insulin may need to be lowered to reduce the risk of hypoglycaemia (low blood sugar levels).

In patients with moderately or severely reduced kidney function the dose of Sitagliptin HCS should be reduced.

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 HCS have been shown in studies?

Because Sitagliptin HCS 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 HCS?

Because Sitagliptin HCS 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 HCS approved?

It was concluded that, in accordance with EU requirements, Sitagliptin HCS has been shown to have comparable quality and to be bioequivalent to Januvia. Therefore, the State Institute for Drug Control decided that, as for 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 HCS?

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

The marketing authorisation for Sitagliptin HCS was granted on 15 May 2023.

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

This summary was last updated in 04-2025.