Summary Public Assessment Report

Generics

Sitagliptin/Metformin HCS 50 mg/850 mg film-coated tablets
Sitagliptin/Metformin HCS 50 mg/1 000 mg film-coated tablets
sitagliptin/metformin hydrochloride

SK/H/0278/001-002/DC

Date: April 2025

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Generics

Sitagliptin/Metformin HCS 50 mg/850 mg film-coated tablets
Sitagliptin/Metformin HCS 50 mg/1000 mg film-coated tablets
(hereinafter Sitagliptin/Metformin HCS)

sitagliptin/metformin hydrochloride, 50 mg/850 mg, 50 mg/1 000 mg, film-coated tablets

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

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

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

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

Sitagliptin/Metformin 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:

- in patients who are not satisfactorily controlled on metformin (an antidiabetic medicine) used on its own.
- in patients who are already taking a combination of sitagliptin and metformin as separate tablets,
- in combination with a sulphonylurea, a PPAR-gamma agonist such as a thiazolidinedione, or insulin (other types of antidiabetic medicine) in patients who are not satisfactorily controlled on this medicine and metformin.

How does Sitagliptin/Metformin 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 substances in Sitagliptin/Metformin HCS, sitagliptin and metformin hydrochloride, each have a different mode of action.

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 the 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.

Metformin works mainly by inhibiting glucose production and reducing its absorption in the gut.

As a result of the action of both active substances, blood glucose levels are reduced, and this helps to control type-2 diabetes.

How is Sitagliptin/Metformin HCS used?

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

Sitagliptin/Metformin HCS is taken twice a day. The strength of tablet to use depends on the dose of the other antidiabetic medicines that the patient was taking before. If Sitagliptin/Metformin HCS is taken with a sulphonylurea or insulin, the dose of the sulphonylurea or insulin may need to be lowered, to avoid hypoglycaemia (low blood sugar levels).

The maximum dose of sitagliptin is 100 mg a day. Sitagliptin/Metformin HCS should be taken with food to avoid any stomach problems caused by metformin.

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/Metformin HCS have been shown in studies?

Because Sitagliptin/Metformin HCS is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Janumet. 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/Metformin HCS?

Because Sitagliptin/Metformin 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/Metformin HCS approved?

It was concluded that, in accordance with EU requirements, Sitagliptin/Metformin HCS 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 reference medicine called Janumet, 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/Metformin HCS?

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

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

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

This summary was last updated in 04-2025.

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