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# Sitagliptin/Metformin hydrochloride Sun (*sitagliptin/metformin hydrochloride*)

An overview of Sitagliptin/Metformin hydrochloride Sun and why it is authorised in the EU

## What is Sitagliptin/Metformin hydrochloride Sun and what is it used for?

Sitagliptin/Metformin hydrochloride Sun is a medicine used to control blood glucose (sugar) levels in adults with type 2 diabetes. It is used together with diet and exercise in the following ways:

- in patients whose blood glucose levels are not satisfactorily controlled with metformin (a diabetes 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 diabetes medicines) in patients whose blood glucose levels are not satisfactorily controlled with these individual medicines and metformin.

Sitagliptin/Metformin hydrochloride Sun contains the active substances sitagliptin and metformin hydrochloride and is a 'generic medicine'. This means that Sitagliptin/Metformin hydrochloride Sun contains the same active substances and works in the same way as a 'reference medicine' already authorised in the EU called Janumet. For more information on generic medicines, see the question-and-answer document here.

## How is Sitagliptin/Metformin hydrochloride Sun used?

Sitagliptin/Metformin hydrochloride Sun is available as tablets and can only be obtained with a prescription. The medicine is taken twice a day and the dose depends on the dose of the other diabetes medicines that the patient was taking before.

If Sitagliptin/Metformin hydrochloride Sun 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).

For more information about using Sitagliptin/Metformin hydrochloride Sun, see the package leaflet or contact your doctor or pharmacist.

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## How does Sitagliptin/Metformin hydrochloride Sun 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 where the body is unable to use insulin effectively. The active substances in Sitagliptin/Metformin hydrochloride Sun each have a different mode of action to help correct this.

Sitagliptin is a dipeptidyl-peptidase-4 (DPP-4) inhibitor. It works by blocking the breakdown of incretin hormones in the body which 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 blood glucose levels are 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.

Together, these actions reduce blood glucose levels which helps to control type 2 diabetes.

## How has Sitagliptin/Metformin hydrochloride Sun been studied?

Studies on the benefits and risks of the active substances in the authorised use have already been carried out with the reference medicine, Janumet, and do not need to be repeated for Sitagliptin/Metformin hydrochloride Sun.

As for every medicine, the company provided data on the quality of Sitagliptin/Metformin hydrochloride Sun. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

## What are the benefits and risks of Sitagliptin/Metformin hydrochloride Sun?

Because Sitagliptin/Metformin hydrochloride Sun is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

## Why is Sitagliptin/Metformin hydrochloride Sun authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Sitagliptin/Metformin hydrochloride Sun has been shown to have comparable quality and to be bioequivalent to Janumet. Therefore, the Agency's view was that, as for Janumet, the benefits of Sitagliptin/Metformin hydrochloride Sun outweigh the identified risks and it can be authorised for use in the EU.

## What measures are being taken to ensure the safe and effective use of Sitagliptin/Metformin hydrochloride Sun?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Sitagliptin/Metformin hydrochloride Sun have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Sitagliptin/Metformin hydrochloride Sun are continuously monitored. Suspected side effects reported with Sitagliptin/Metformin hydrochloride Sun are carefully evaluated and any necessary action taken to protect patients.

## Other information about Sitagliptin/Metformin hydrochloride Sun

Sitagliptin/Metformin hydrochloride Sun received a marketing authorisation valid throughout the EU on 31 March 2023.

Further information on Sitagliptin/Metformin hydrochloride Sun can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/sitagliptin-metformin-hydrochloride-Sun. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 02-2023.