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Sitagliptin Accord (*sitagliptin*)

An overview of Sitagliptin Accord and why it is authorised in the EU

What is Sitagliptin Accord and what is it used for?

Sitagliptin Accord 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:

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

Sitagliptin Accord contains the active substance sitagliptin and is a 'generic medicine'. This means that Sitagliptin Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Januvia. For more information on generic medicines, see the question-and-answer document here.

How is Sitagliptin Accord used?

Sitagliptin Accord is available as tablets and can only be obtained with a prescription. The recommended dose is 100 mg once a day. The dose may be lowered in some patients with reduced kidney function. If Sitagliptin Accord 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 glucose levels).

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For more information about using Sitagliptin Accord, see the package leaflet or contact your doctor or pharmacist.

How does Sitagliptin Accord 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 Accord, 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 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. Together, these processes reduce blood glucose levels and help to control type 2 diabetes.

How has Sitagliptin Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Januvia, and do not need to be repeated for Sitagliptin Accord.

As for every medicine, the company provided data on the quality of Sitagliptin Accord. The company also carried out a study 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 Accord?

Because Sitagliptin Accord 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 Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Sitagliptin Accord has been shown to have comparable quality and to be bioequivalent to Januvia. Therefore, the Agency's view was that, as for Januvia, the benefits of Sitagliptin Accord 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 Accord?

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

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

Other information about Sitagliptin Accord

Sitagliptin Accord received a marketing authorisation valid throughout the EU on 25 April 2022.

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

This overview was last updated in 05-2022.