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Sitagliptin/Metformin hydrochloride Mylan (*sitagliptin/metformin hydrochloride*)

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

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

Sitagliptin/Metformin hydrochloride Mylan 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 either of these medicines and metformin.

Sitagliptin/Metformin hydrochloride Mylan contains the active substances sitagliptin and metformin hydrochloride and is a 'generic medicine'. This means that Sitagliptin/Metformin hydrochloride Mylan 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 Mylan used?

Sitagliptin/Metformin hydrochloride Mylan is available as tablets and can only be obtained with a prescription. The medicine is taken twice a day and the strength of the tablet depends on the dose of the other diabetes medicines that the patient was taking before. If Sitagliptin/Metformin hydrochloride Mylan 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 hydrochloride Mylan should be taken with food to avoid any stomach problems caused by metformin.

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

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How does Sitagliptin/Metformin hydrochloride Mylan 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 Mylan 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 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 processes reduce blood glucose levels and help to control type 2 diabetes.

How has Sitagliptin/Metformin hydrochloride Mylan 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 Mylan.

As for every medicine, the company provided data on the quality of Sitagliptin/Metformin hydrochloride Mylan. 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 Mylan?

Because Sitagliptin/Metformin hydrochloride Mylan 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 Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Sitagliptin/Metformin hydrochloride Mylan 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 Mylan 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 Mylan?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Sitagliptin/Metformin hydrochloride Mylan 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 Mylan are continuously monitored. Suspected side effects reported with Sitagliptin/Metformin hydrochloride Mylan are carefully evaluated and any necessary action taken to protect patients.

Other information about Sitagliptin/Metformin hydrochloride Mylan

Sitagliptin/Metformin hydrochloride Mylan received a marketing authorisation valid throughout the EU on 16 February 2022.

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

This overview was last updated in 02-2022.