



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Vildagliptin/Metformin hydrochloride Accord (vildagliptin / metformin hydrochloride)

An overview of Vildagliptin/Metformin hydrochloride Accord and why it is authorised in the EU

### **What is Vildagliptin/Metformin hydrochloride Accord and what is it used for?**

Vildagliptin/Metformin hydrochloride Accord is a diabetes medicine that is used in addition to diet and exercise to improve control of blood glucose (sugar) levels in adults with type 2 diabetes. It is used:

- in patients whose blood glucose levels are not adequately controlled by metformin alone;
- in patients who are already taking a combination of vildagliptin and metformin as separate tablets;
- together with other diabetes medicines, including insulin, when these medicines do not provide adequate control of blood glucose.

Vildagliptin/Metformin hydrochloride Accord is a 'generic medicine'. This means that it contains the same active substances and works in the same way as a 'reference medicine' already authorised in the EU called Eucreas. For more information on generic medicines, see the question-and-answer document [here](#).

Vildagliptin/Metformin hydrochloride Accord contains the active substances vildagliptin and metformin hydrochloride.

### **How is Vildagliptin/Metformin hydrochloride Accord used?**

Vildagliptin/Metformin hydrochloride Accord is available as tablets and the recommended dose is one tablet twice a day (one in the morning and one in the evening). The starting tablet strength depends on the patient's current treatment and the expected effects of Vildagliptin/Metformin hydrochloride Accord. Taking Vildagliptin/Metformin hydrochloride Accord with or just after food may reduce any stomach problems caused by metformin.

The doctor should carry out tests to check the patient's kidney and liver function before treatment with Vildagliptin/Metformin hydrochloride Accord and at regular intervals during treatment.

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**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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The medicine can only be obtained with a prescription. For more information about using Vildagliptin/Metformin hydrochloride Accord, see the package leaflet or contact your doctor or pharmacist.

## **How does Vildagliptin/Metformin hydrochloride Accord work?**

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the glucose level in the blood or the body is unable to use insulin effectively. Vildagliptin/Metformin hydrochloride Accord contains two active substances, each with a different mode of action.

Vildagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor that 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 blocking the breakdown of incretin hormones in the blood, vildagliptin prolongs their action, stimulating the pancreas to produce more insulin when blood glucose levels are high. Vildagliptin does not work when the blood glucose is low. Vildagliptin 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 substances, the blood glucose is reduced, which helps to control type 2 diabetes.

## **How has Vildagliptin/Metformin hydrochloride Accord 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, Eucreas, and do not need to be repeated for Vildagliptin/Metformin hydrochloride Accord.

As for every medicine, the company provided studies on the quality of Vildagliptin/Metformin hydrochloride Accord. 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 Vildagliptin/Metformin hydrochloride Accord?**

Because Vildagliptin/Metformin hydrochloride 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 Vildagliptin/Metformin hydrochloride Accord authorised in the EU?**

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

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

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

## **Other information about Vildagliptin/Metformin hydrochloride Accord**

Further information on Vildagliptin/Metformin hydrochloride Accord can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/vildagliptinmetformin-hydrochloride-accord](https://ema.europa.eu/medicines/human/EPAR/vildagliptinmetformin-hydrochloride-accord)

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 02-2022.