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Zomarist (*vildagliptin / metformin hydrochloride*)

An overview of Zomarist and why it is authorised in the EU

What is Zomarist and what is it used for?

Zomarist is a diabetes medicine that is used together with diet and exercise to control the blood glucose (sugar) in adults with type 2 diabetes. It is used:

- in patients whose blood glucose is insufficiently controlled with metformin alone;
- in patients who are already taking the 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.

Zomarist contains the active substances vildagliptin and metformin hydrochloride. This medicine is the same as Eucreas, which is already authorised in the EU. The company that makes Eucreas has agreed that its scientific data can be used for Zomarist (informed consent).

How is Zomarist used?

Zomarist is available as tablets (50 mg/850 mg and 50 mg/1,000 mg) 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 Zomarist. Taking Zomarist 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 Zomarist and at regular intervals during treatment.

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

How does Zomarist 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. Zomarist 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

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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.

What benefits of Zomarist have been shown in studies?

Vildagliptin on its own is approved for use in the EU under the name Galvus, and metformin has been available in the EU since 1959. Vildagliptin can be used with metformin in type 2 diabetes patients who are not satisfactorily controlled on metformin alone.

Studies with Galvus as an add-on to metformin, metformin and a sulphonylurea, or metformin and insulin have been used to support the use of Zomarist in the same indications. The studies compared Galvus with placebo (a dummy treatment) and measured the levels of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled.

Vildagliptin has been shown to be more effective than placebo at reducing HbA1c levels when it was added to metformin. Patients adding vildagliptin had falls in HbA1c levels of 0.88 percentage points after 24 weeks from a starting level of 8.38%. In contrast, patients adding placebo had smaller changes in HbA1c levels, with a rise of 0.23 percentage points from a starting level of 8.3%. In other studies, vildagliptin in combination with metformin has been shown to be more effective than placebo when used with a sulphonylurea or insulin.

The applicant also presented the results of two studies showing that the active substances in the two strengths of Zomarist were absorbed in the body in the same way as when they were taken as separate tablets.

What are the risks associated with Zomarist?

The most common side effects with Zomarist (seen in more than 1 patient in 10) are nausea (feeling sick), vomiting, diarrhoea, abdominal (belly) pain and loss of appetite. For the full list of all side effects reported with Zomarist, see the package leaflet.

Zomarist must not be used in people who are hypersensitive (allergic) to vildagliptin, metformin or any of the other ingredients. Zomarist must also not be used in patients with certain kidney, liver or heart problems or those who could develop metabolic acidosis (build-up of acid in the blood). It must also not be used in patients who consume excessive amounts of alcohol or who have alcoholism, or in women who are breastfeeding. For the full list of restrictions, see the package leaflet.

Why is Zomarist authorised in the EU?

Studies have shown that vildagliptin taken with metformin is effective in reducing blood glucose levels and that the combination of vildagliptin and metformin was effective as an add-on to a sulphonylurea or insulin. The combination of the two active substances vildagliptin and metformin in one tablet may help patients to stick to their treatment. The European Medicines Agency therefore decided that Zomarist's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Zomarist?

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

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

Other information about Zomarist

Zomarist received a marketing authorisation valid throughout the EU on 1 December 2008.

Further information on Zomarist can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zomarist.

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