LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Vimetso
(vildagliptin, metformin hydrochloride)

SE/H/2027/01-02/DC

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Summary Public Assessment Report

Vimetso
metformin hydrochloride, vildagliptin

Film-coated tablet, 50 mg/850 mg, 50 mg/1000 mg

This is a summary of the public assessment report (PAR) for Vimetso. It explains how Vimetso was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Vimetso.

For practical information about using Vimetso, patients should read the package leaflet or contact their doctor or pharmacist.

What is Vimetso and what is it used for?

Vimetso is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Eucreas.

Vimetso is used to treat adult patients with type 2 diabetes. This type of diabetes is also known as noninsulin- dependent diabetes mellitus. Vimetso is used when diabetes cannot be controlled by diet and exercise alone and/or with other medicines used to treat diabetes (insulin or sulphonylureas).

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Both insulin and glucagon are made in the pancreas. Insulin helps to lower the level of sugar in the blood, especially after meals. Glucagon triggers the liver to make sugar, causing the blood sugar level to rise.

How does Vimetso work?

Both active substances, vildagliptin and metformin, help to control the level of sugar in the blood. The substance vildagliptin works by making the pancreas produce more insulin and less glucagon. The substance metformin works by helping the body to make better use of insulin. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes.

How is Vimetso used?

The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Vimetso have been shown in studies?

Because Vimetso is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Eucreas.

What are the possible side effects from Vimetso?

Because Vimetso is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Vimetso approved?

It was concluded that, in accordance with EU requirements, Vimetso has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Eucreas. Therefore, the Swedish Medical Products Agency decided that, as for Eucreas, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that Vimetso is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Vimetso including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Vimetso

The full PAR for Vimetso can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Vimetso, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2022-05.