Summary Public Assessment Report

Generics

Linagliptin Viatris/Ilinpru
linagliptin

SK/H/0302-0303/001/DC

Date: 04/2024

Summary Public Assessment Report

Generics

Linagliptin Viatris/Ilinpru

Linagliptin, film-coated tablets, 5 mg

This is a summary of the public assessment report (PAR) for Linagliptin Viatris/Ilinpru. It explains how Linagliptin Viatris/Ilinpru 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 Linagliptin Viatris/Ilinpru.

For practical information about using Linagliptin Viatris/Ilinpru, patients should read the package leaflet or contact their doctor or pharmacist.

What is Linagliptin Viatris/Ilinpru and what is it used for?

Linagliptin Viatris/Ilinpru is a 'generic medicine'. This means that Linagliptin Viatris/Ilinpru is similar to a 'reference medicine' already authorised in the European Union (EU) called Trajenta 5 mg film-coated tablets.

Linagliptin Viatris/Ilinpru is used in the treatment of 'type 2 diabetes' in adults, if the disease cannot be adequately controlled with one oral anti-diabetic medicine (metformin or sulphonylureas) or diet and exercise alone. Linagliptin Viatris/Ilinpru may be used together with other anti-diabetic medicines e.g., metformin, sulphonylureas (e.g., glimepiride, glipizide), empagliflozin, or insulin.

It is important to keep following the advice about diet and exercise that you have been given by your doctor or nurse.

How does Linagliptin Viatris/Ilinpru work?

Linagliptin Viatris/Ilinpru contains the active substance linagliptin which belongs to a group of medicines called "oral anti-diabetics". Oral anti-diabetics are used to treat high blood sugar levels. They work by helping the body reduce the level of sugar in your blood.

How is Linagliptin Viatris/Ilinpru used?

The pharmaceutical form of Linagliptin Viatris/Ilinpru is film-coated tablets and the route of administration is oral.

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

The medicine can only be obtained with a prescription.

What benefits of Linagliptin Viatris/Ilinpru have been shown in studies?

Because Linagliptin Viatris/Ilinpru is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Trajenta 5 mg film-coated tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

Applicant submitted two identical marketing authorisation applications (duplicates), which were approved under the names of Linagliptin Viatris and Ilinpru.

What are the possible side effects of Linagliptin Viatris/Ilinpru?

Because Linagliptin Viatris/Ilinpru is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of restrictions, see the package leaflet.

Why is Linagliptin Viatris/Ilinpru approved?

It was concluded that, in accordance with EU requirements, Linagliptin Viatris/Ilinpru has been shown to have comparable quality and to be bioequivalent to reference medicine. Therefore, the State Institute for Drug Control decided that, as for reference medicine called Trajenta 5 mg film-coated tablets, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Linagliptin Viatris/Ilinpru?

A risk management plan has been developed to ensure that Linagliptin Viatris/Ilinpru 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 Linagliptin Viatris/Ilinpru, 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 Linagliptin Viatris/Ilinpru

The marketing authorisation for Linagliptin Viatris was granted on 03.04.2024.
The marketing authorisation for Ilinpru was granted on 05.04.2024.

The full PAR for Linagliptin Viatris/Ilinpru can be found on the website https://www.sukl.sk/. For more information about treatment with Linagliptin Viatris/Ilinpru, read the package leaflet (*sukl.sk*) or contact your doctor or pharmacist.

This summary was last updated in 04/2024.