STATE INSTITUTE FOR DRUG CONTROL
Kvetna 11, 825 08 Bratislava 26, Slovak Republic

CMDh/305/2013
March 2018, Rev.02

Summary Public Assessment Report

Generics

Mapoli 25 mg/ml oral solution

sitagliptin hydrochloride monohydrate

SK/H/0261/001/DC

Date: 05/2022

Summary Public Assessment Report

Generics

Mapoli 25 mg/ml oral solution

sitagliptin, oral solution, 25 mg/ml

This is a summary of the public assessment report (PAR) for Mapoli 25 mg/ml oral solution. It explains how Mapoli 25 mg/ml oral solution 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 Mapoli 25 mg/ml oral solution.

For practical information about using Mapoli 25 mg/ml oral solution, patients should read the package leaflet or contact their doctor or pharmacist.

What is Mapoli 25 mg/ml oral solution and what is it used for?

Mapoli 25 mg/ml oral solution is a 'generic medicine'. This means that Mapoli 25 mg/ml oral solution is similar to a 'reference medicine' already authorised in the European Union (EU) called Januvia 100 mg film coated tablets.
Mapoli 25 mg/ml oral solution is used in the treatment of type 2 diabetes.

It helps to increase the levels of insulin produced after a meal and decreases the amount of sugar made by the body.

How does Mapoli 25 mg/ml oral solution work?

Mapoli 25 mg/ml oral solution contains the active substance sitagliptin which is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

How is Mapoli 25 mg/ml oral solution used?

The pharmaceutical form of Mapoli 25 mg/ml is oral solution 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 usual recommended dose is:
- 100 mg (4 ml oral solution)
- once a day
- by mouth

The medicine can only be obtained with a prescription.

What benefits of Mapoli 25 mg/ml oral solution have been shown in studies?
Because Mapoli 25 mg/ml oral solution is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Januvia 100 mg

film coated tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Mapoli 25 mg/ml oral solution?

Because Mapoli 25 mg/ml oral solution 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 Mapoli 25 mg/ml oral solution approved?

It was concluded that, in accordance with EU requirements, Mapoli 25 mg/ml oral solution 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 Januvia, 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 Mapoli 25 mg/ml oral solution?

A risk management plan has been developed to ensure that Mapoli 25 mg/ml oral solution 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 Mapoli 25 mg/ml oral solution, 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 Mapoli 25 mg/ml oral solution.

The marketing authorisation for Mapoli 25 mg/ml oral solution was granted on 24.01.2022 in the RMS.

The full PAR for Mapoli 25 mg/ml oral solution can be found on the website ŠÚKL. For more information about treatment with Mapoli 25 mg/ml oral solution, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in 05-2022.