Summary Public Assessment Report

Generics

Maysiglu 25 mg film-coated tablets
Maysiglu 50 mg film-coated tablets
Maysiglu 100 mg film-coated tablets

Sitagliptin Krka 25 mg film-coated tablets
Sitagliptin Krka 50 mg film-coated tablets
Sitagliptin Krka 100 mg film-coated tablets

Sitagavia 25 mg film-coated tablets
Sitagavia 50 mg film-coated tablets
Sitagavia 100 mg film-coated tablets

Sitagliptin TAD 25 mg film-coated tablets
Sitagliptin TAD 50 mg film-coated tablets
Sitagliptin TAD 100 mg film-coated tablets

sitagliptin

SK/H/0207/001-003/DC
SK/H/0211/001-003/DC
SK/H/0212/001-003/DC
SK/H/0213/001-003/DC

Date: 06/2020

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* (Name **Sitagliptin Krka** is used throughout this report and it refers to all above stated authorized medical products.)

Sitagliptin, film coated tablets, 25 mg/50mg/100mg

This is a summary of the public assessment report (PAR) for *Sitagliptin Krka**. It explains how *Sitagliptin Krka* 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 *Sitagliptin Krka*.

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

What is *Sitagliptin Krka* and what is it used for?
Sitagliptin Krka is a 'generic medicine'. This means that *Sitagliptin Krka* is similar to a 'reference medicine' already authorised in the European Union (EU) called Januvia 25 mg, 50 mg, and 100 mg film-coated tablets.

Sitagliptin Krka 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.

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

This medicine helps to lower blood sugar, which is too high because of type 2 diabetes. It can be used alone or in combination with certain other medicines (insulin, metformin, sulphonylureas, or glitazones) that lower blood sugar, which may already be taking for diabetes together with a food and exercise plan.

How does *Sitagliptin Krka* work?
Sitagliptin Krka 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 *Sitagliptin Krka* used?
The pharmaceutical form of *Sitagliptin Krka* is film coated tablet 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 *Sitagliptin Krka* have been shown in studies?
Because *Sitagliptin Krka* is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Januvia 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 *Sitagliptin Krka*?
Because *Sitagliptin Krka* 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 *Sitagliptin Krka* approved?
It was concluded that, in accordance with EU requirements, *Sitagliptin Krka* has been shown to have comparable quality and to be bioequivalent to reference medicine Januvia. 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 *Sitagliptin Krka*?
A risk management plan has been developed to ensure that *Sitagliptin Krka* 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 *Sitagliptin Krka*, 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 *Sitagliptin Krka*
The marketing authorisation for
Maysiglu 25 mg, 50 mg and 100 mg film coated tablets,
Sitagliptin Krka 25 mg, 50 mg and 100 mg film coated tablets,
Sitagavia 25 mg, 50 mg and 100 mg film coated tablets
was granted on 16.3.2020

The marketing authorisation for **Sitagliptin TAD** 25 mg, 50 mg and 100 mg film coated tablets was granted on 22.04.2020

The full PAR for *Sitagliptin Krka* can be found on the website of the ŠUKL.

For more information about treatment with above mentioned medical products, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 06-2020.