

# Summary Public Assessment Report

## Generics

**Sitagliptin/Metformin Krka 50 mg/850 mg film-coated tablets**  
**Sitagliptin/Metformin Krka 50 mg/1000 mg film-coated tablets**

**SIATGAVIA MET 50 mg/850 mg film-coated tablets**  
**SITAGAVIA MET 50 mg/1000 mg film-coated tablets**

**Maymetsi 50 mg/850 mg film-coated tablets**  
**Maymetsi 50 mg/1000 mg film-coated tablets**

**sitagliptin/metformin hydrochlorid**

**SK/H/0240/001-002/DC**  
**SK/H/0241/001-002/DC**  
**SK/H/0242/001-002/DC**

**Date: 03/2021**

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

sitagliptin/metformin hydrochlorid, film-coated tablets, 50mg/850 mg; 50mg/1000mg

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

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

### What is Sitagliptin/Metformin Krka and what is it used for?

Sitagliptin/Metformin Krka is a ‘generic medicine’. This means that Sitagliptin/Metformin Krka is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Janumet.

Sitagliptin/Metformin Krka is used in the treatment of adult patients with type 2 diabetes mellitus

Along with diet and exercise, Sitagliptin/Metformin Krka helps lower the blood sugar.

Sitagliptin/Metformin Krka can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas, or glitazones).

### How does Sitagliptin/Metformin Krka work?

Sitagliptin/Metformin Krka contains two different medicines called sitagliptin and metformin.

- sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors)
- metformin belongs to a class of medicines called biguanides.

They work together to control blood sugar levels in adult patients with a form of diabetes called ‘type 2 diabetes mellitus’. This medicine helps to increase the levels of insulin produced after a meal and lowers the amount of sugar made by the body.

### **How is Sitagliptin/Metformin Krka used?**

The pharmaceutical form of Sitagliptin/Metformin Krka 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 Sitagliptin/Metformin Krka have been shown in studies?**

Because Sitagliptin/Metformin Krka is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Janumet. 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/Metformin Krka?**

Because Sitagliptin/Metformin 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/Metformin Krka approved?**

It was concluded that, in accordance with EU requirements, Sitagliptin/Metformin Krka has been shown to have comparable quality and to be bioequivalent/be comparable to Janumet. Therefore, the State Institute for Drug Control decided that, as for reference medicine called Janumet, 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/Metformin Krka?**

A risk management plan has been developed to ensure that Sitagliptin/Metformin 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/Metformin 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/Metformin Krka**

The marketing authorisation for  
Sitagliptin/Metformin Krka 50 mg/850 mg film-coated tablets  
Sitagliptin/Metformin Krka 50 mg/1000 mg film-coated tablets

SIATGAVIA MET 50 mg/850 mg film-coated tablets  
SITAGAVIA MET 50 mg/1000 mg film-coated tablets

Maymetsi 50 mg/850 mg film-coated tablets  
Maymetsi 50 mg/1000 mg film-coated tablets

was granted on 09.02.2021

The full PAR for Sitagliptin/Metformin Krka can be found on the website [ŠUKL](#). For more information about treatment with Sitagliptin/Metformin Krka, read the package leaflet ([link](#)) or contact your doctor or pharmacist.

This summary was last updated in 03/2021.