

# **Summary Public Assessment Report**

## **Generics**

**Paracetamol/Kofein Xantis 500 mg/65 mg**  
*Paracetamol/Coffeinum*

**SK/H/0166/001/DC**

**Date: August 2018**

# Summary Public Assessment Report

## Generics

Paracetamol/Kofein Xantis 500 mg/65 mg

Paracetamol/ Caffeine  
tablets  
500 mg/ 65 mg

This is a summary of the public assessment report (PAR) for Paracetamol/Kofein Xantis 500 mg/65 mg. It explains how Paracetamol/Kofein Xantis 500 mg/65 mg 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 Paracetamol/Kofein Xantis 500 mg/65 mg.

For practical information about using Paracetamol/Kofein Xantis 500 mg/65 mg, patients should read the package leaflet or contact their doctor or pharmacist.

### **What is Paracetamol/Kofein Xantis 500 mg/65 mg and what is it used for?**

Paracetamol/Kofein Xantis 500 mg/65 mg is a 'generic medicine'. This means that Paracetamol/Kofein Xantis 500 mg/65 mg is similar to a 'reference medicine' already authorised in the European Union (EU) called Panadol Extra.

Paracetamol/Kofein Xantis 500 mg/65 mg contains the combination of two active substances – paracetamol and caffeine, which are effective against pain and fever.

Paracetamol relieves pain and decreases increased body temperature. Caffeine potentiates analgesic effect of paracetamol, reduces fatigue, slightly supports breathing and blood circulation in febrile diseases.

Paracetamol/Kofein Xantis 500 mg/65 mg is suitable for the relief of headache, migraine, backache, toothache and period pain. Paracetamol/Kofein Xantis 500 mg/65 mg also relieves the unpleasant influenza and cold symptoms such as muscle or joint pain, sore throat and decreases fever.

### **How does Paracetamol/Kofein Xantis 500 mg/65 mg work?**

Paracetamol relieves pain and decreases increased body temperature. Caffeine potentiates analgesic effect of paracetamol, reduces fatigue, slightly supports breathing and blood circulation in febrile diseases.

### **How is Paracetamol/Kofein Xantis 500 mg/65 mg used?**

The pharmaceutical form of Paracetamol/Kofein Xantis 500 mg/65 mg is 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.

Adults and adolescents over 15 years

1 – 2 tablets up to 4 times a day as needed with frequency at least 4 hours. Single tablet is suitable for patients with body weight 34 to 60 kg; two tablets for patients with body weight over 60 kg. The maximum single dose are two tablets. Do not take more than 8 tablets in 24 hours.

Use in children and adolescents (12 – 15 years)

1 tablet up to 3 times daily as needed with dose frequency at least 6 hours. The maximum single dose is one tablet. Do not take more than 3 tablets in 24 hours.

The medicine can be obtained without a prescription.

### **What benefits of Paracetamol/Kofein Xantis 500 mg/65 mg have been shown in studies?**

Because Paracetamol/Kofein Xantis 500 mg/65 mg is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Panadol Extra. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

### **What are the possible side effects of Paracetamol/Kofein Xantis 500 mg/65 mg?**

Because Paracetamol/Kofein Xantis 500 mg/65 mg 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 Paracetamol/Kofein Xantis 500 mg/65 mg approved?**

It was concluded that, in accordance with EU requirements, Paracetamol/Kofein Xantis 500 mg/65 mg has been shown to have comparable quality and to be bioequivalent to Panadol Extra. Therefore, the State Institute for Drug Control decided that, as for Panadol Extra, 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 Paracetamol/Kofein Xantis 500 mg/65 mg?**

A risk management plan has been developed to ensure that Paracetamol/Kofein Xantis 500 mg/65 mg 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 Paracetamol/Kofein Xantis 500 mg/65 mg, 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 Paracetamol/Kofein Xantis 500 mg/65 mg**

The marketing authorisation for Paracetamol/Kofein Xantis 500 mg/65 mg was granted on 23.05.2016.

The full PAR for Paracetamol/Kofein Xantis 500 mg/65 mg can be found on the [ŠÚKL website](#). For more information about treatment with Paracetamol/Kofein Xantis 500 mg/65 mg, read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 08-2018.