

Summary Public Assessment Report
non-generics

Paracetamol/Kofein Xantis 1000 mg/130 mg tablety

Paracetamol/Caffeine

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Paracetamol/ Caffeine

Tablets

1000 mg/ 130 mg

This is a summary of the public assessment report (PAR) for Paracetamol/Kofein Xantis 1000 mg/130 mg tablety.

It explains how Paracetamol/Kofein Xantis 1000 mg/130 mg tablety 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 1000 mg/130 mg tablety.

For practical information about using Paracetamol/Kofein Xantis 1000 mg/130 mg tablety, patients should read the package leaflet or contact their doctor or pharmacist.

What is Paracetamol/Kofein Xantis 1000 mg/130 mg tablety and what is it used for?

Paracetamol/Kofein Xantis 1000 mg/130 mg tablety is a ‘hybrid generic medicine’. This means that it is similar to a reference medicine containing the same active substance, but it has another strength.

The company has provided additional own data to demonstrate the safety and efficacy of Paracetamol/Kofein Xantis 1000 mg/130 mg tablety regarding this difference from the reference medicine.

The reference medicine for Paracetamol/Kofein Xantis 1000 mg/130 mg tablety is Panadol Extra Novum.

Paracetamol/Kofein Xantis 1000 mg/130 mg tablety 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 1000 mg/130 mg tablety is suitable for the relief of headache, migraine, backache, toothache and period pain. Paracetamol/Kofein Xantis 1000 mg/130 mg tablety also relieves the unpleasant influenza and cold symptoms such as muscle or joint pain, sore throat and decreases fever.

How does Paracetamol/Kofein Xantis 1000 mg/130 mg tablety 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 1000 mg/130 mg tablety used?

The pharmaceutical form of Paracetamol/Kofein Xantis 1000 mg/130 mg tablety 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 with body weight over 60 kg

1 tablet up to 4 times a day as needed with frequency at least 4 hours. The maximum single dose is one tablet. Do not take more than 4 tablets in 24 hours. Patients with impaired liver or renal function should talk to the doctor regarding recommendation lower dose. The tablets should be swallowed whole with water.

The medicine can only be obtained with a prescription.

What benefits of Paracetamol/Kofein Xantis 1000 mg/130 mg tablety have been shown in studies?

Because Paracetamol/Kofein Xantis 1000 mg/130 mg tablety is a hybrid application and is considered to be therapeutically equivalent, to the reference product Panadol Extra Novum, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Paracetamol/Kofein Xantis 1000 mg/130 mg tablety?

For the full list of all side effects reported with Paracetamol/Kofein Xantis 1000 mg/130 mg tablety, see section 4 of the package leaflet.

Patients should contact the doctor before taking Paracetamol/Kofein Xantis 1000 mg/130 mg tablety:

- if they suffer from low red blood cell count (hemolytic anemia),
- if they have lack of glucose-6-phosphate dehydrogenase (hereditary condition leading to low red blood cell counts),
- if they have liver or kidney disease (including alcoholic liver disease)
- if they have problems with alcohol. Long-term consumption of alcohol significantly increases the risk of toxic liver impairment by paracetamol, while the highest risk is in patients with short-term abstinence (12 hours).

For the full list of restrictions, see the package leaflet.

Why is Paracetamol/Kofein Xantis 1000 mg/130 mg tablety approved?

The State Institute for Drug Control decided that Paracetamol/Kofein Xantis 1000 mg/130 mg tablety's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Paracetamol/Kofein Xantis 1000 mg/130 mg tablety?

A risk management plan has been developed to ensure that Paracetamol/Kofein Xantis 1000 mg/130 mg tablety 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 1000 mg/130 mg tablety, 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 1000 mg/130 mg tablety

The marketing authorisation for Paracetamol/Kofein Xantis 1000 mg/130 mg tablety was granted on 19.07.2018.

The full PAR for Paracetamol/Kofein Xantis 1000 mg/130 mg tablety can be found on the [ŠÚKL website](#). For more information about treatment with Paracetamol/Kofein Xantis 1000 mg/130 mg tablety, read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 07-2018.