

Summary Public Assessment Report
non-generics

Acetylsalicylic acid Xantis 100 mg
Acetylsalicylic acid

SK/H/0187/001/DC

Date: 05.02.2018

Summary Public Assessment Report

non-generics

Kyselina acetylsalicylová Xantis 100 mg

acetylsalicylic acid, tablets, 100 mg

This is a summary of the public assessment report (PAR) for Kyselina acetylsalicylová Xantis 100 mg. It explains how Kyselina acetylsalicylová Xantis 100 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 Kyselina acetylsalicylová Xantis 100 mg.

For practical information about using Kyselina acetylsalicylová Xantis 100 mg, patients should read the package leaflet or contact their doctor or pharmacist.

What is Kyselina acetylsalicylová Xantis 100 mg and what is it used for?

Kyselina acetylsalicylová Xantis 100 mg is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of Kyselina acetylsalicylová Xantis 100 mg is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Kyselina acetylsalicylová Xantis 100 mg contains acetylsalicylic acid. Acetylsalicylic acid in lower doses prevents the formation of blood clots, prevents clogging of arteries, which can result in severe heart diseases (heart attack) or cerebral diseases (stroke).

Kyselina acetylsalicylová Xantis 100 mg is used in standard treatment of unstable angina pectoris (chest pain) or acute myocardial infarction (heart attack). Kyselina acetylsalicylová Xantis 100 mg can be used as prevention of re-infarction after surgery or other interventions on arteries and as prevention or transient ischemic attack (TIA) (called also “mini stroke”) or strokes after previous signs.

Kyselina acetylsalicylová Xantis 100 mg is not indicated for the treatment of pain.

How does Kyselina acetylsalicylová Xantis 100 mg work?

By reducing production of thromboxane (substance produced by platelets), acetylsalicylic acid reduces the risk of clots forming in the blood. A blood clot that forms inside a blood vessel can be dangerous because it can block the blood supply to an organ. A blockage in the arteries supplying blood to the heart or brain can cause a heart attack or stroke. Taking daily low dose of acetylsalicylic acid (75-150mg) helps prevent these types of blood clots.

How is Kyselina acetylsalicylová Xantis 100 mg used?

The pharmaceutical form of Kyselina acetylsalicylová Xantis 100 mg is tablet and the route of administration is oral use.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Swallow whole tablets with sufficient amount of liquid. Take after meal.

The score line is only to facilitate breaking for ease swallowing and not to divide into equal doses.

Unstable angina pectoris

Daily dose is 100 – 300 mg acetylsalicylic acid. For better tolerance is recommended 1 tablet daily (corresponds to 100 mg acetylsalicylic acid).

Acute heart attack (myocardial infarction)

Recommended dose is 1 tablet daily (corresponds to 100 mg acetylsalicylic acid). For the treatment of acute myocardial infarction first tablet should be chewed.

Prevention of re-infarction

Recommended dose are 3 tablets daily (corresponds to 300 mg acetylsalicylic acid).

After surgery or other intervention on arteries (e.g after ACVB - aortocoronary venous bypass, during PTCA - percutaneous transluminal coronary angioplasty)

Daily dose is 100 – 300 mg acetylsalicylic acid. For better tolerance is recommended 1 tablet daily (corresponds to 100 mg acetylsalicylic acid). The best time to start treatment by Kyselina acetylsalicylová Xantis 100 mg after ACVB is 24 hours after surgery.

Prevention of transient ischemic attacks (TIA) and strokes after previous signs

Daily dose is 100 – 300 mg of acetylsalicylic acid. For better tolerance is recommended 1 tablet daily (corresponds to 100 mg of acetylsalicylic acid).

Use in elderly

Elderly who are more prone to adverse events should take Kyselina acetylsalicylová Xantis 100 mg with caution. To elderly suffering from impaired kidney or liver function is recommended dosage adjustment.

Use in paediatric population

Kyselina acetylsalicylová Xantis 100 mg is not suitable for children and adolescents under 16 years.

If you take more Kyselina acetylsalicylová Xantis 100 mg than you should

If you or someone else swallow too many tablets at the same time or you think child may have swallowed any contact your doctor or go to nearest hospital casualty department.

Symptoms of overdose may include ringing in ears, hearing problems, headache, dizziness, confusion, nausea, vomiting and abdominal pain. A large overdose can lead to more rapid breathing than normal (hyperventilation), fever, excess sweating, restlessness, seizures, hallucinations, low blood sugar, coma and shock.

The medicine can only be obtained with a prescription.

What benefits of Kyselina acetylsalicylová Xantis 100 mg have been shown in studies?

As acetylsalicylic acid is a well-known substance, and its use in the treatment of *unstable angina pectoris, acute heart attack, prevention of re-infarction, after surgery or other intervention on arteries, prevention of transient ischemic attacks (TIA) and strokes after previous signs* is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of acetylsalicylic acid in the treatment of *unstable angina pectoris, acute heart attack, prevention of re-infarction, after surgery or other intervention on arteries, prevention of transient ischemic attacks (TIA) and strokes after previous signs*.

What are the possible side effects from Kyselina acetylsalicylová Xantis 100 mg?

The common side effects with Kyselina acetylsalicylová Xantis 100 mg (which may affect more than 1 in 10 people) are

- dyspepsia
- gastrointestinal and abdominal pain

For the full list of all side effects reported with Kyselina acetylsalicylová Xantis 100 mg, see section 4 of the package leaflet.

Do not take Kyselina acetylsalicylová Xantis 100 mg:

- if you are allergic to acetylsalicylic acid, other salicylates or any of the other ingredients of this medicine (listed in section 6)
- if you have suffered from allergic reaction with asthma attack in history or similar reaction to salicylates or other nonsteroidal anti-inflammatory drugs
- if you have a history of stomach ulcer (chronic or recurrent) or bleeding to stomach or intestine or other kinds of bleeding such as cerebrovascular haemorrhages (bleeding from a ruptured blood vessel in the brain) in history
- if you have unusual tendency to bleed (hemorrhagic diathesis such as hemophilia or trombocytopenia)
- if you have gout
- if you have severe kidney or liver problems
- if you have severe heart failure
- in combination with methotrexate in doses exceeding 15 mg/week
- if you are in your last 3 months of pregnancy; you must not use higher doses than 100 mg per day

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

Why is Kyselina acetylsalicylová Xantis 100 mg approved?

The State Institute for Drug Control decided that Kyselina acetylsalicylová Xantis 100 mg 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 Kyselina acetylsalicylová Xantis 100 mg?

A risk management plan has been developed to ensure that Kyselina acetylsalicylová Xantis 100 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 Kyselina acetylsalicylová Xantis 100 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 Kyselina acetylsalicylová Xantis 100 mg

The marketing authorisation for Kyselina acetylsalicylová Xantis 100 mg was granted on 25.01.2018.

The full PAR for Kyselina acetylsalicylová Xantis 100 mg can be found on the website

http://www.sukl.sk/buxus/generate_page.php?page_id=386&lie_id=6820C

For more information about treatment with Kyselina acetylsalicylová Xantis 100 mg, read the package leaflet

http://www.sukl.sk/buxus/generate_page.php?page_id=637&dok_id=483682

or contact your doctor or pharmacist.

This summary was last updated in 02/2018.