LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Allopurinol Mylan
(allopurinol)

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Allopurinol Mylan
(allopurinol)

Tablet 100 mg and 300 mg

This is a summary of the public assessment report (PAR) for Allopurinol Mylan. It explains how Allopurinol Mylan 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 Allopurinol Mylan.

For practical information about using Allopurinol Mylan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Allopurinol Mylan and what is it used for?

Allopurinol Mylan is a 'generic medicine'. This means that Allopurinol Mylan is similar to a 'reference medicine' already authorised in the European Union (EU) called Zyloric.

Allopurinol Mylan is used in conditions where your body produces too much uric acid. These may include gout or kidney stones or some other types of kidney problems or when you are having treatment for cancer. In gout the uric acid builds up in your joints and tendons as crystals that may cause inflammation, swelling and pain.

How does Allopurinol Mylan work?

Allopurinol Mylan contains a medicine called allopurinol. It works by slowing down the speed of certain chemical reactions in your body to lower the level of uric acid in your blood and urine and prevents the formation of uric acid crystals.

How is Allopurinol Mylan used?

The pharmaceutical form of Allopurinol Mylan is tablet for oral use.

Please read section 3 of the package leaflet 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 Allopurinol Mylan have been shown in studies?

Because Allopurinol Mylan is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Zyloric. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Allopurinol Mylan?

Because Allopurinol Mylan 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 Allopurinol Mylan approved?

It was concluded that, in accordance with EU requirements, Allopurinol Mylan has been shown to have comparable quality and to be bioequivalent to the reference medicine Zyloric. Therefore, the Medical Products Agency in Sweden decided that, as for Zyloric, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Allopurinol Mylan?

A risk management plan has been developed to ensure that Allopurinol Mylan 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 Allopurinol Mylan, 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 Allopurinol Mylan

The marketing authorisation for Allopurinol Mylan was granted on 2018-01-12 in Sweden.

The full PAR for Allopurinol Mylan can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Allopurinol Mylan, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2018-01.