LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Urogerolan
(febuxostat)

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(febuxostat)

Film-coated tablets; 80 mg and 120 mg

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

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

What is Urogerolan and what is it used for?

Urogerolan is a ‘generic medicine’. This means that Urogerolan is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Adenuric.

Urogerolan tablets contain the active substance febuxostat and are used to treat gout, which is associated with an excess of a chemical called uric acid (urate) in the body. In some people, the amount of uric acid builds up in the blood and may become too high to remain soluble. When this happens, urate crystals may form in and around the joints and kidneys. These crystals can cause sudden, severe pain, redness, warmth and swelling in a joint (known as a gout attack). Left untreated, larger deposits called tophi may form in and around joints. These tophi may cause joint and bone damage.

Urogerolan 120 mg tablets is also used to treat and prevent high blood levels of uric acid that may occur when you start to receive chemotherapy for blood cancers.
When chemotherapy is given, cancer cells are destroyed, and uric acid levels increase in the blood accordingly, unless the formation of uric acid is prevented.

Urogerolan is for adults.

How does Urogerolan work?

Urogerolan works by reducing uric acid levels. Keeping uric acid levels low by taking Urogerolan once every day stops crystals building up, and over time it reduces symptoms. Keeping uric acid levels sufficiently low for a long enough period can also shrink tophi.

How is Urogerolan used?

The pharmaceutical form of Urogerolan 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 Urogerolan have been shown in studies?

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

What are the possible side effects of Urogerolan?

Because Urogerolan 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 Urogerolan approved?

It was concluded that, in accordance with EU requirements, Urogerolan has been shown to have comparable quality and to be bioequivalent to the reference medicine Adenuric. Therefore, the Medical Products Agency in Sweden decided that, as for Adenuric, 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 Urogerolan?

A risk management plan has been developed to ensure that Urogerolan 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 Urogerolan, 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 Urogerolan

The marketing authorisation for Urogerolan was granted on 2017-10-02 in Sweden.

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

This summary was last updated in 2017-10.