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EPAR summary for the public

Febuxostat Mylan

febuxostat

This is a summary of the European public assessment report (EPAR) for Febuxostat Mylan. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Febuxostat Mylan.

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

What is Febuxostat Mylan and what is it used for?

Febuxostat Mylan is a medicine used to treat adults with long-term hyperuricaemia (high levels of uric acid or 'urate' in the blood). Hyperuricaemia can lead to urate crystals forming and building up in the joints and the kidneys. When this happens in the joints and causes pain, it is known as 'gout'. Febuxostat Mylan is used in patients who have signs of a build-up of crystals, including gouty arthritis (pain and inflammation in the joints) or tophi ('stones', larger deposits of urate crystals that can cause joint and bone damage).

Febuxostat Mylan is also used to treat and prevent high levels of uric acid in the blood in adults with blood cancers who are receiving chemotherapy (medicines to treat cancer) and at risk of tumour lysis syndrome (a complication due to the breakdown of cancer cells causing a sudden rise of uric acid in the blood which can cause damage to the kidneys).

Febuxostat Mylan contains the active substance febuxostat and is a 'generic medicine'. This means that Febuxostat Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Adenuric. For more information on generic medicines, see the question-and-answer document here.

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How is Febuxostat Mylan used?

Febuxostat Mylan is available as tablets (80 and 120 mg) and can only be obtained with a prescription.

For the treatment of long-term hyperuricaemia, the recommended dose of Febuxostat Mylan is 80 mg once a day. This usually reduces blood uric acid levels within two weeks, but the dose can be increased to 120 mg once a day if blood uric acid levels remain high (above 6 mg per decilitre) after two to four weeks. Attacks of gout can still occur during the first few months of treatment, so it is recommended that patients take other medicines to prevent attacks of gout for at least the first six months of treatment with Febuxostat Mylan. Febuxostat Mylan treatment should not be stopped if an attack of gout occurs.

For the prevention and treatment of hyperuricaemia in patients undergoing chemotherapy, the recommended dose is 120 mg once a day. Febuxostat Mylan should be started 2 days before chemotherapy and continued for at least 7 days.

How does Febuxostat Mylan work?

The active substance in Febuxostat Mylan, febuxostat, reduces the formation of uric acid. It works by blocking an enzyme called xanthine oxidase, which is needed to make uric acid in the body. By reducing the production of uric acid, Febuxostat Mylan can reduce levels of uric acid in the blood and keep them low, stopping crystals from building up. This can reduce the symptoms of gout. Keeping uric acid levels low for long enough can also shrink tophi. In patients who are on chemotherapy a reduction in uric acid levels is expected to reduce the risk of tumour lysis syndrome.

How has Febuxostat Mylan been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Adenuric, and do not need to be repeated for Febuxostat Mylan.

As for every medicine, the company provided studies on the quality of Febuxostat Mylan. The company also carried out a study that showed that it is ‘bioequivalent’ to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Febuxostat Mylan?

Because Febuxostat Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine’s.

Why is Febuxostat Mylan approved?

The Agency’s Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Febuxostat Mylan has been shown to have comparable quality and to be bioequivalent to Adenuric. Therefore, the CHMP’s view was that, as for Adenuric, the benefit outweighs the identified risk. The Committee recommended that Febuxostat Mylan be approved for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Febuxostat Mylan have been included in the summary of product characteristics and the package leaflet.

Other information about Febuxostat Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Febuxostat Mylan on 15 June 2017.

The full EPAR for Febuxostat Mylan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Febuxostat Mylan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 06-2017.