EMA/110881/2019
EMEA/H/C/004773

Febuxostat Krka (*febuxostat*)

An overview of Febuxostat Krka and why it is authorised in the EU

What is Febuxostat Krka and what is it used for?

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

How is Febuxostat Krka used?

Febuxostat Krka 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 Krka is 80 mg once a day. This usually reduces blood uric acid levels within 2 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 2 to 4 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 6 months of treatment with Febuxostat Krka. Febuxostat Krka treatment should not be stopped if an attack of gout occurs.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union

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

For more information about using Febuxostat Krka, see the package leaflet or contact your doctor or pharmacist.

How does Febuxostat Krka work?

The active substance in Febuxostat Krka, 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 Krka 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 Krka been studied?

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

As for every medicine, the company provided studies on the quality of Febuxostat Krka. 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 Krka?

Because Febuxostat Krka 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 Krka authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Febuxostat Krka has been shown to have comparable quality and to be bioequivalent to Adenuric. Therefore, the Agency's view was that, as for Adenuric, the benefit of Febuxostat Krka outweighs the identified risk and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Febuxostat Krka are continuously monitored. Side effects reported with Febuxostat Krka are carefully evaluated and any necessary action taken to protect patients.

Other information about Febuxostat Krka

Febuxostat Krka received a marketing authorisation valid throughout the EU on 28 March 2019.

Further information on Febuxostat Krka can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/febuxostat-krka. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 03-2019.