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EPAR summary for the public

Adenuric

febuxostat

This is a summary of the European public assessment report (EPAR) for Adenuric. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Adenuric.

What is Adenuric?

Adenuric is a medicine that contains the active substance febuxostat. It is available as tablets (80 and 120 mg).

What is Adenuric used for?

Adenuric is 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'. Adenuric is used in patients who already 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).

Adenuric is also used to treat and prevent high levels of uric acid in the blood in adults with blood cancers who are on chemotherapy 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).

The medicine can only be obtained with a prescription.

How is Adenuric used?

For the treatment of long-term hyperuricaemia, the recommended dose of Adenuric is 80 mg once a day. This usually reduces blood uric acid levels within two weeks, but the dose can be increased to 120

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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 Adenuric. Adenuric 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. Adenuric should be started two days before chemotherapy and continued for at least 7 days.

How does Adenuric work?

The active substance in Adenuric, 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, Adenuric 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 Adenuric been studied?

For the treatment of hyperuricaemia and gout, Adenuric has been studied in two main studies involving a total of 1,834 patients. The first study, carried out in 1,072 patients, compared three doses of Adenuric (80, 120 and 240 mg once a day) with placebo (a dummy treatment) and allopurinol (another medicine used to treat hyperuricaemia). The study lasted six months. The second study compared two doses of Adenuric (80 and 120 mg once a day) with allopurinol over one year in 762 patients.

In both studies, allopurinol was used at a dose of 300 mg once a day, except in patients with kidney problems, who took 100 mg. The main measure of effectiveness was the number of patients whose final three blood uric acid levels were below 6 mg/dl. Blood uric acid levels were measured every month.

For the prevention and treatment of hyperuricaemia in patients undergoing chemotherapy, Adenuric has been studied in one main study involving 346 adult patients undergoing chemotherapy for blood cancer. Patients received either Adenuric or allopurinol for 7 to 9 days. The main measure of effectiveness was based on their blood uric acid levels.

What benefit has Adenuric shown during the studies?

Adenuric was more effective than allopurinol and placebo in treating hyperuricaemia by reducing blood uric acid levels. In the first study, 48% of the patients taking 80 mg Adenuric once a day (126 out of 262) and 65% of the patients taking 120 mg once a day (175 out of 269) had levels of uric acid below 6 mg/dl in the final three measurements. This was compared with 22% of the patients taking allopurinol (60 out of 268) and none of the 134 patients taking placebo. Similar results were seen in the second study after a year.

In patients with blood cancer who were undergoing chemotherapy, Adenuric was as effective as allopurinol in controlling blood levels of uric acid: in 98.3 % of patients (170 out of 173) on Adenuric blood levels of uric acid normalised compared with 96 % (166 out of 173) of patients on allopurinol.

What is the risk associated with Adenuric?

The most commonly reported side effects with Adenuric are gout flare-ups, abnormal liver test results, diarrhoea, nausea (feeling sick), headache, rash and oedema (swelling). These side effects were mostly mild or moderate in severity. Rare serious hypersensitivity (allergic) reactions to Adenuric have occurred post-marketing.

For the full list of all side effects and restrictions with Adenuric, see the package leaflet.

Why has Adenuric been approved?

The CHMP concluded that Adenuric was more effective than allopurinol at lowering blood uric acid levels including in patients undergoing chemotherapy , but that it could carry a greater risk of side effects affecting the heart and blood vessels. The Committee decided that Adenuric's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Adenuric 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 Adenuric, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Adenuric

The European Commission granted a marketing authorisation valid throughout the European Union for Adenuric on 21 April 2008.

The full EPAR for Adenuric 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 Adenuric, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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