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EPAR summary for the public

Zurampic

lesinurad

This is a summary of the European public assessment report (EPAR) for Zurampic. 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 Zurampic.

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

What is Zurampic and what is it used for?

Zurampic is a medicine used in adults with gout to reduce high levels of uric acid in the blood. It is used in combination with a xanthine oxidase inhibitor, another type of gout medicine, when the xanthine oxidase inhibitor on its own is not able to control uric acid levels sufficiently.

Gout results from a build-up of uric acid crystals in and around the joints, especially in the toes, which causes pain and swelling.

Zurampic contains the active substance lesinurad.

How is Zurampic used?

Zurampic is available as 200-mg tablets. The recommended dose is 200 mg once daily, taken in the morning at the same time as a xanthine oxidase inhibitor medicine such as allopurinol or febuxostat.

Patients should drink plenty of fluids throughout the day. If treatment with the xanthine oxidase inhibitor is interrupted, then treatment with Zurampic must also be interrupted at the same time.

The medicine can only be obtained with a prescription.



How does Zurampic work?

The active substance in Zurampic, lesinurad, helps to remove uric acid from the body. It does this by blocking a protein called 'uric acid transporter-1' (URAT1) in the kidneys. URAT1 normally allows some uric acid to return to the blood after the kidneys have filtered it out. By blocking URAT1, more uric acid is passed out in the urine and less remains in the blood.

Zurampic is used in combination with a xanthine oxidase inhibitor such as allopurinol or febuxostat. Xanthine oxidase inhibitors reduce the production of uric acid in the body. Thus, adding Zurampic to treatment with a xanthine oxidase inhibitor lowers uric acid levels further. This prevents the build-up of uric acid in joints where it can cause pain, swelling and joint damage.

What benefits of Zurampic have been shown in studies?

Zurampic was studied in two main studies involving over 1,200 adults with gout who were previously treated with allopurinol. Their blood level of uric acid was not sufficiently controlled with allopurinol alone and was above 60 mg/litre at the start of the study. These studies compared the effect of adding Zurampic or placebo (a dummy treatment) to patients' allopurinol treatment. The main measure of effectiveness was the number of patients whose blood level of uric acid dropped below 60 mg/litre after 6 months of treatment. Adding Zurampic 200 mg once daily was effective in 55% (222 of 405) patients. This compared with 26% (104 of 407) in patients who took placebo in addition to allopurinol.

A third main study involved 324 adults who had at least one measurable tophus (large deposit of uric acid in or around a joint or under the skin) and with high blood levels of uric acid (over 80 mg/litre without gout medicines or above 60 mg/litre despite treatment with allopurinol or febuxostat). Patients were first treated with febuxostat alone for three weeks and then with febuxostat plus either Zurampic or placebo. The main measure of effectiveness was the number of patients whose blood level of uric acid dropped below 50 mg/litre after 6 months of treatment. Overall, Zurampic 200 mg once daily was effective in 57% (60 of 106) patients. This compared with 47% (51 of 109) patients given placebo. Looking just at patients whose blood uric acid level did not fall sufficiently on treatment with febuxostat alone, the level dropped to less than 50 mg/litre in 44% (26 of 59) patients taking Zurampic compared to 24% (12 of 51) patients taking placebo.

What are the risks associated with Zurampic?

The most common side effects with Zurampic (which may affect up to 1 in 10 people) are flu, headache, heartburn and (gastro-oesophageal reflux disease) stomach acid coming back to the mouth, and blood tests showing increased blood creatinine levels (a marker of kidney function). The most serious adverse reactions were kidney failure, reduced kidney function, and kidney stones, which affected less than 1 patient in 100. For the full list of all side effects reported with Zurampic, see the package leaflet.

Patients must not take Zurampic if they suffer from tumour lysis syndrome (a complication due to the rapid breakdown of cancer cells during cancer treatment) or a rare hereditary disease called Lesch-Nyhan syndrome, both of which raise uric acid levels in the blood. Patients with very poor kidney function or who have had a kidney transplant must also not take Zurampic. For the full list of restrictions, see the package leaflet.

Why is Zurampic approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Zurampic's benefits are greater than its risks and recommended that it be approved for use in the EU. Combined

with a xanthine oxidase inhibitor, Zurampic reduced blood levels of uric acid in patients with gout whose high uric acid levels were not sufficiently controlled by a xanthine oxidase inhibitor. Over time, visible deposits of uric acid disappeared in increasing number of patients continuing Zurampic and febuxostat treatment, and fewer patients had recurrence of gout attacks. Risks such as kidney damage or heart problems are addressed in the product information.

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

The patient's kidney function will be monitored regularly during treatment with Zurampic and the doctor will advise the patient to take sufficient fluid during the day and always take Zurampic with either allopurinol or febuxostat, which helps to prevent kidney damage from Zurampic.

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

The company that markets Zurampic will carry out a study on the risk of heart, circulation or kidney disorders in patients treated with Zurampic, particularly in those who have previously suffered from such disorders. This is because these disorders have occurred during treatment with Zurampic.

Further information can be found in the [summary of the risk management plan](#).

Other information about Zurampic

The European Commission granted a marketing authorisation valid throughout the European Union for Zurampic on 18 February 2016.

The full EPAR and risk management plan summary for Zurampic 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 Zurampic, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2016.