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Duzallo (*allopurinol / lesinurad*)

An overview of Duzallo and why it is authorised in the EU

What is Duzallo and what is it used for?

Duzallo is a medicine used in adults with gout to reduce high levels of uric acid in the blood. It is used when allopurinol 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.

Duzallo contains the active substances allopurinol and lesinurad.

How is Duzallo used?

Duzallo is available as tablets containing either 200 or 300 mg of allopurinol in combination with 200 mg of lesinurad. The strength of Duzallo tablet is chosen to match the dose of allopurinol the patient has been taking. The recommended dose is one tablet once daily, in the morning.

Patients should drink plenty of water throughout the day. The medicine can only be obtained with a prescription. For more information about using Duzallo, see the package leaflet or contact your doctor or pharmacist.

How does Duzallo work?

The two active substances in Duzallo work in different ways to prevent the build-up of uric acid:

- Lesinurad helps to remove uric acid from the body by blocking a protein called 'uric acid transporter 1' (URAT1) in the kidneys. URAT1 allows 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.
- Allopurinol reduces the production of uric acid in the body by blocking an enzyme called xanthine oxidase, which is needed to make uric acid in the body. By reducing the production of uric acid, allopurinol can reduce levels of uric acid in the blood and keep them low, stopping crystals from building up.

Lesinurad has been authorized in the EU as Zurampic since 2016. Allopurinol has been marketed in the EU since the 1960s.

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What benefits of Duzallo have been shown in studies?

Two main studies showed that the combination of allopurinol and lesinurad can help lower uric acid levels when allopurinol on its own is not working well enough.

The two studies involved over 800 adults with gout whose blood level of uric acid was high (above 65 mg/litre) despite allopurinol treatment. Adding lesinurad 200 mg once daily to the treatment led to 55% patients having levels below 60 mg/litre after 6 months. This compared with 26% of patients who received placebo (a dummy treatment) in addition to allopurinol.

In addition two studies were carried out to show that Duzallo produced similar levels of active substances in the blood to the active substances given separately.

What are the risks associated with Duzallo?

The most common side effects with Duzallo (which may affect up to 1 in 10 people) are flu, gastro-oesophageal reflux disease (stomach acid coming back to the mouth), headache 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 side effects reported with Duzallo, see the package leaflet.

Duzallo must not be taken by patients with severely reduced kidney function, including those who have severely impaired kidney function, who are on dialysis or have received a kidney transplant. It must also not be taken in patients with tumour lysis syndrome (a complication due to the rapid breakdown of cancer cells during cancer treatment) or Lesch-Nyhan syndrome (a rare genetic disease). For the full list of restrictions, see the package leaflet.

Why is Duzallo authorised in the EU?

The European Medicines Agency decided that Duzallo's benefits are greater than its risks and it can be authorised for use in the EU.

The active substances in Duzallo have already been shown to be effective when used as separate tablets. Two main studies showed that lesinurad in combination with allopurinol reduced the blood levels of uric acid in gout patients in whom allopurinol alone was not sufficient. Combining the active substances in a single tablet has the advantage of simplifying treatment. The safety profile of Duzallo is similar to the individual components.

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

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

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

Other information about Duzallo

Duzallo received a marketing authorisation valid throughout the EU on 23 August 2018.

Further information on Duzallo can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 08-2018.