EMA/707287/2018
EMEA/H/C/000805

Ranexa[1] (*ranolazine*)

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

What is Ranexa and what is it used for?

Ranexa is a medicine used to treat the symptoms of stable angina pectoris (chest pain caused by reduced blood flow to the heart). It is used as an add-on to existing treatment in patients whose disease is not adequately controlled by other medicines, such as beta blockers or calcium antagonists, or in patients who cannot take these medicines.

Ranexa contains the active substance ranolazine.

How is Ranexa used?

Ranexa can only be obtained with a prescription and is available as prolonged-release tablets (375 mg, 500 mg and 750 mg). 'Prolonged release' means that ranolazine is released slowly from the tablet over a few hours.

The recommended starting dose of Ranexa is 375 mg twice a day. After two to four weeks, the dose should be increased to 500 mg twice a day, and then to 750 mg twice a day, depending on the patient's response. The maximum dose is 750 mg twice a day. Doses may need to be lower in patients who have certain side effects. Dose increases should be carried out carefully in the elderly, in patients who weigh less than 60 kg, and in patients who have problems with their kidneys, liver or heart.

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

How does Ranexa work?

The active substance in Ranexa, ranolazine, is thought to work by reducing the flow of calcium ions into the heart muscle cells. Calcium ions normally cause the heart muscle to contract. By reducing the flow of calcium into the cells, ranolazine is thought to help the heart to relax, improving blood flow to the heart muscle and relieving the symptoms of angina pectoris.

[1] Previously known as Latixa

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

What benefits of Ranexa have been shown in studies?

Ranexa has been investigated in one main study involving 823 patients with an average age of 64 years who had had angina pectoris for at least three months. In the study, two doses of Ranexa (750 and 1,000 mg twice a day) were compared with placebo (a dummy treatment) as an add-on to commonly used medicines for angina pectoris (atenolol, amlodipine or diltiazem). Ranexa was shown to be more effective than placebo at increasing the length of time the patients could exercise. At the start of the study, the patients could exercise for about 7 minutes. After 12 weeks, this increased by an average of 1 minute 56 seconds in the patients adding either dose of Ranexa, and by an average of 1 minute 32 seconds in those adding placebo.

What are the risks associated with Ranexa?

The most common side effects with Ranexa (which may affect up to 1 in 10 people) are dizziness, headache, constipation, vomiting, nausea (feeling sick) and weakness. For the full list of side effects of Ranexa, see the package leaflet.

Ranexa must not be used in patients who have severe problems with their kidneys or moderate or severe problems with their liver. It must also not be used in patients who are taking other medicines that are broken down in the same way as ranolazine, or certain other medicines that are used to correct the heart rhythm. For the full list of restrictions, see the package leaflet.

Why is Ranexa authorised in the EU?

The European Medicines Agency noted that the effectiveness of Ranexa in improving the symptoms of patients with stable angina pectoris is modest but that it could be of value in patients who have not responded fully to other medicines. The Agency therefore decided that Ranexa's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Ranexa

Ranexa received a marketing authorisation valid throughout the EU on 9 July 2008.

Further information on Ranexa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Ranexa

This overview was last updated in 10-2018.