

**Ranexa<sup>1</sup>**  
*ranolazine***EPAR summary for the public**

*This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.*

*If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).*

**What is Ranexa?**

Ranexa is a medicine that contains the active substance ranolazine. It is available as oval prolonged-release tablets (blue: 375 mg; orange: 500 mg; green: 750 mg). 'Prolonged release' means that ranolazine is released slowly from the tablet over a few hours.

**What is Ranexa used for?**

Ranexa is 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 for angina pectoris, such as beta-blockers or calcium antagonists, or in patients who cannot take these medicines.

The medicine can only be obtained with a prescription.

**How is Ranexa used?**

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. Ranexa tablets should be swallowed whole and should not be broken, crushed or chewed. They can be taken with or without food.

Patients who take Ranexa must be given a 'patient alert card' that summarises the key safety information on the medicine.

**How does Ranexa work?**

The active substance in Ranexa, ranolazine, is thought to work by reducing the flow of sodium ions into the heart muscle cells. This interferes with the activity of special channels on the cell surface called 'sodium-dependent calcium channels' through which calcium ions normally enter the cells. This reduces the number of calcium ions that enter the 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.

---

<sup>1</sup> Previously known as Latixa.

**How has Ranexa been studied?**

Ranexa has been studied in one main study including a total of 823 patients with an average age of 64 years who had had angina pectoris for at least three months. Two doses of Ranexa (750 and 1000 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). The main measure of effectiveness was how long patients could exercise after 12 weeks of treatment, compared with before treatment.

**What benefit has Ranexa shown during the studies?**

Ranexa was 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 is the risk associated with Ranexa?**

The most common side effects with Ranexa (seen in between 1 and 10 patients in 100) are dizziness, headache, constipation, vomiting, nausea (feeling sick) and asthenia (weakness). For the full list of all side effects reported with Ranexa, see the Package Leaflet.

Ranexa should not be used in people who may be hypersensitive (allergic) to ranolazine or any of the other ingredients. It 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 these medicines, see the Package Leaflet.

**Why has Ranexa been approved?**

The Committee for Medicinal Products for Human Use (CHMP) 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 Committee decided that Ranexa's benefits are greater than its risks as an add-on treatment of the symptoms of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line anti-anginal medicines (such as beta-blockers and/or calcium antagonists). The Committee recommended that Ranexa be given marketing authorisation.

**Which measures are being taken to ensure the safe use of Ranexa?**

The company that makes Ranexa will agree on the wording of the patient alert card in each Member State. The card will be inserted in the boxes containing the tablets and will include information for patients and healthcare workers explaining how to use the medicine safely.

**Other information about Ranexa:**

The European Commission granted a marketing authorisation valid throughout the European Union for Latixa on 9 July 2008. The name of the medicine was changed to Ranexa on 11 August 2008. The marketing authorisation holder is Menarini International Operations Luxembourg S.A.

The full EPAR for Ranexa can be found [here](#).

**This summary was last updated in 09-2009.**