European Medicines Agency

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Ariclaim
duloxetine

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 Ariclaim?
Ariclaim is a medicine that contains the active substance duloxetine. It is available as gastroresistant capsules (white and blue: 30 mg; green and blue: 60 mg). 'Gastroresistant' means that the capsules' contents pass through the stomach without being broken down until they reach the intestine. This prevents the active substance being destroyed by the acid in the stomach.

What is Ariclaim used for?
Ariclaim is used to treat pain due to diabetic peripheral neuropathy (damage to the nerves in the extremities that can occur in patients with diabetes).
The medicine can only be obtained with a prescription.

How is Ariclaim used?
The recommended dose of Ariclaim is 60 mg once a day, but some patients may need a higher dose of 120 mg per day. The response to treatment should be assessed two months after starting treatment. If the treatment is effective, it should then be evaluated at least every three months. Ariclaim can be taken with or without food. The dose should be reduced gradually when stopping treatment.

How does Ariclaim work?
The active substance in Ariclaim, duloxetine, is a serotonin-noradrenaline re-uptake inhibitor. It works by preventing the neurotransmitters 5-hydroxytrypamine (also called serotonin) and noradrenaline from being taken back up into nerve cells in the brain and spinal cord. Neurotransmitters are chemicals that allow nerve cells to communicate with one another. By blocking their re-uptake, duloxetine increases the amount of these neurotransmitters in the spaces between these nerve cells, increasing the level of communication between the cells. Since these neurotransmitters are involved in reducing the sensation of pain, blocking their re-uptake into nerve cells may improve the symptoms of neuropathic pain.

How has Ariclaim been studied?
Ariclaim has been studied in two 12-week studies in 809 diabetic adults who had had pain every day for at least six months. Three different doses of Ariclaim were compared with placebo. The main measure of effectiveness was the change in the severity of pain each week, as recorded by the patients on an 11-point scale in daily diaries.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

What benefit has Ariclaim shown during the studies?
Ariclaim at doses of 60 mg once or twice a day was more effective at reducing pain than placebo. In both studies, pain reduction was seen from the first week of treatment for up to 12 weeks, with patients taking Ariclaim having pain scores between 1.17 and 1.45 points lower than those taking placebo.

What is the risk associated with Ariclaim?
The most common side effects with Ariclaim (seen in more than 1 patient 10) are headache, somnolence (sleepiness), dizziness, nausea and dry mouth. Most of these were mild or moderate, starting early in treatment and getting milder as treatment continued. For the full list of all side effects reported with Ariclaim, see the Package Leaflet.
Ariclaim should not be used in people who may be hypersensitive (allergic) to duloxetine or any of the other ingredients. Ariclaim must not be used in patients with certain types of liver disease or with severe kidney disease. It must not be used together with monoamine oxidase inhibitors (a group of antidepressants), fluvoxamine (another antidepressant), or ciprofloxacin or enoxacin (types of antibiotic). Treatment must not be started in patients with uncontrolled high blood pressure, because of a risk of hypertensive crisis (sudden, dangerously high blood pressure).

Why has Ariclaim been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Ariclaim's benefits are greater than its risks for the treatment of diabetic peripheral neuropathic pain in adults. The Committee recommended that Ariclaim be given marketing authorisation.
Ariclaim was originally also authorised at strengths of 20 and 40 mg for the treatment of moderate to severe stress urinary incontinence (SUI) in women, but the company withdrew these strengths when the marketing authorisation was renewed in August 2009. SUI is accidental leaks of urine during physical exertion or when coughing, laughing, sneezing, lifting or exercising.

Other information about Ariclaim:
The European Commission granted a marketing authorisation valid throughout the European Union for Ariclaim on 11 August 2004. The marketing authorisation holder is Eli Lilly Nederland BV. The marketing authorisation was renewed on 11 August 2009.

The full EPAR for Ariclaim is available here.

This summary was last updated in 08-2009.