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EPAR summary for the public

Duloxetine Lilly

duloxetine

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

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

What is Duloxetine Lilly and what is it used for?

Duloxetine Lilly is a medicine that is used to treat adults with the following diseases:

- major depression;
- pain due to diabetic peripheral neuropathy (damage to the nerves in the extremities that can occur in patients with diabetes);
- generalised anxiety disorder (long-term anxiety or nervousness about everyday matters).

This medicine contains the active substance duloxetine and is the same as Cymbalta, which is already authorised in the European Union (EU). The company that makes Cymbalta has agreed that its scientific data can be used for Duloxetine Lilly ('informed consent').

How is Duloxetine Lilly used?

Duloxetine Lilly is available as gastroresistant capsules (30 mg and 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. The medicine can only be obtained with a prescription.

For major depression, the recommended dose of Duloxetine Lilly is 60 mg once a day. A response is usually seen in two to four weeks. In patients who respond to Duloxetine Lilly, treatment should

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continue for several months to prevent the disease coming back, or for longer in patients who have had repeated periods of depression in the past.

For diabetic neuropathic pain, the recommended dose is 60 mg per day but some patients may need a higher dose of 120 mg per day. The response to treatment should be assessed regularly.

For generalised anxiety disorder, the recommended starting dose is 30 mg once a day, but the dose can be increased to 60, 90 or 120 mg depending on the patient's response. Most patients will need to take 60 mg per day. Patients who also have major depression should start with 60 mg once a day. In patients who respond to Duloxetine Lilly, treatment should continue for several months, to prevent the disorder coming back.

The dose of Duloxetine Lilly should be reduced gradually when stopping treatment.

How does Duloxetine Lilly work?

The active substance in this medicine, duloxetine, is a serotonin-noradrenaline re-uptake inhibitor. It works by preventing the neurotransmitters 5-hydroxytryptamine (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 maintaining high mood and reducing the sensation of pain, blocking their re-uptake into nerve cells can improve the symptoms of depression, anxiety and neuropathic pain.

What benefits of Duloxetine Lilly have been shown in studies?

For major depression, Duloxetine Lilly has been compared with placebo (a dummy treatment) in eight main studies involving a total of 2,544 patients. Six of the studies looked at the treatment of depression and measured the change in symptoms over up to six months. The other two studies looked at how long it took for symptoms to return in patients who had initially responded to Duloxetine Lilly, including 288 patients with a history of repeated episodes of depression for up to five years. Although the results of the depression studies varied, Duloxetine Lilly was more effective than placebo in four of the studies. In the two studies where the approved dose of Duloxetine Lilly was compared with placebo, Duloxetine Lilly was more effective. It also took longer for symptoms to return in patients taking Duloxetine Lilly than in those taking placebo.

For neuropathic pain, Duloxetine Lilly has been compared with placebo in two 12-week studies in 809 diabetic adults. The main measure of effectiveness was the change in the severity of pain each week. These studies showed that Duloxetine Lilly 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.

For generalised anxiety disorder, Duloxetine Lilly has been compared with placebo in five studies involving a total of 2,337 patients. Four studies looked at the treatment of the disorder by measuring the reduction in symptoms after nine to 10 weeks. The fifth study looked at how long it took for symptoms to return in 429 patients who had initially responded to Duloxetine Lilly. Duloxetine Lilly was shown to be more effective than placebo at treating the disorder and preventing symptoms returning.

What are the risks associated with Duloxetine Lilly?

The most common side effects with Duloxetine Lilly (which may affect more than 1 in 10 people) are nausea (feeling sick), headache, dry mouth, somnolence (sleepiness) and dizziness. Most of these are mild or moderate, starting early in treatment and getting milder as treatment continues. For the full list of all side effects reported with Duloxetine Lilly, see the package leaflet.

Duloxetine Lilly must not be used together with monoamine oxidase inhibitors (another group of antidepressants), fluvoxamine (another antidepressant), or ciprofloxacin or enoxacin (types of antibiotics). Duloxetine Lilly must also not be used in patients with reduced liver function or patients with severely reduced kidney function. Treatment must not be started in patients with uncontrolled hypertension (high blood pressure), because of a risk of hypertensive crisis (sudden, dangerously high blood pressure).

For the full list of restrictions, see the package leaflet.

Why is Duloxetine Lilly approved?

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

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

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

Further information can be found in the summary of the risk management plan.

Other information about Duloxetine Lilly

The European Commission granted a marketing authorisation valid throughout the European Union for Duloxetine Lilly on 8 December 2014.

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

This summary was last updated in 12-2014.