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Nodetrip[1] (*duloxetine*)

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

Medicinal Product no longer authorised

What is Nodetrip and what is it used for?

Nodetrip is a medicine used to treat adults with the following diseases:

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

Nodetrip contains the active substance duloxetine.

How is Nodetrip used?

Nodetrip 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 from being destroyed by the acid in the stomach. The medicine can only be obtained with a prescription.

For major depression, the recommended dose is 60 mg once a day. A response is usually seen in two to four weeks. In patients who respond to Nodetrip, treatment should 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 Nodetrip, treatment should continue for several months, to prevent the disorder coming back.

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

[1] Previously known as Xeristar.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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How does Nodetrip work?

The active substance in Nodetrip, 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 Nodetrip have been shown in studies?

Major depression

Nodetrip has been compared with placebo (a dummy treatment) in eight main studies involving a total of 2,544 patients with major depression. 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 Nodetrip, including 288 patients with a history of repeated episodes of depression for up to five years. Although the results of the depression studies varied, Nodetrip was more effective than placebo in four of the studies. It also took longer for symptoms to return in patients taking Nodetrip than in those taking placebo.

Neuropathic pain

Nodetrip was more effective at reducing pain than 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. In both studies, pain reduction was seen from the first week of treatment for up to 12 weeks.

Generalised anxiety disorder

Nodetrip was shown to be more effective than placebo at treating the disorder and preventing symptoms returning in five studies involving a total of 2,337 patients.

Four studies measured the reduction in symptoms after 9 to 10 weeks.

The fifth study looked at how long it took for symptoms to return in 429 patients who had initially responded to Nodetrip.

What are the risks associated with Nodetrip?

The most common side effects with Nodetrip (which may affect more than 1 in 10 people) are nausea (feeling sick), headache, dry mouth, somnolence (sleepiness) and dizziness. For the full list of side effects of Nodetrip, see the package leaflet.

Nodetrip must not be used together with monoamine oxidase inhibitors (another group of antidepressants), fluvoxamine (another antidepressant), or ciprofloxacin or enoxacin (types of antibiotics). Nodetrip 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.

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Why is Nodetrip authorised in the EU?

The European Medicines Agency decided that Nodetrip'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 Nodetrip?

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

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

Other information about Nodetrip

Xeristar received a marketing authorisation valid throughout the EU on 17 December 2004. The name of the medicine was changed to Nodetrip on 29 September 2020.

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

This overview was last updated in 10-2020.

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