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EPAR summary for the public

Leganto

rotigotine

This is a summary of the European public assessment report (EPAR) for Leganto. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Leganto.

What is Leganto?

Leganto is a range of transdermal patches (patches that deliver a medicine across the skin). Each patch releases 1, 2, 3, 4, 6 or 8 mg of the active substance rotigotine over 24 hours.

This medicine is the same as Neupro, which is already authorised in the European Union (EU). The company that makes Neupro has agreed that its scientific data can be used for Leganto ('informed consent').

What is Leganto used for?

Leganto is used to treat the symptoms of the following diseases in adults:

- Parkinson's disease. Leganto is used on its own in early-stage disease, or in combination with levodopa (another medicine used in Parkinson's disease) at any stage of the disease, including the later stages when levodopa starts becoming less effective;
- moderate to severe restless legs syndrome, a disorder where the patient has uncontrollable urges to move the limbs to stop uncomfortable, painful or odd sensations in the body, usually at night. Leganto is used when a specific cause for the disorder cannot be identified.

The medicine can only be obtained with a prescription.

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How is Leganto used?

Leganto is applied once a day at about the same time every day. The patch is applied to dry, clean, healthy skin on the abdomen (tummy), thigh, hip, side, shoulder or upper arm. The patch remains on the skin for 24 hours and is then replaced by a new one in a different place. The same place must not be used again until two weeks later. The strength of patch to use at the start of treatment depends on the type and stage of the disease being treated. The dose can then be increased every week until an effective dose is reached. A special pack with patches of four different strengths is available to help when starting treatment for early-stage Parkinson's disease. The maximum dose is 8 mg/24 h for early-stage Parkinson's disease and 16 mg/24 h for advanced disease. For restless legs syndrome, the maximum dose is 3 mg/24 h.

How does Leganto work?

The active substance in Leganto, rotigotine, is a dopamine agonist, which means that it imitates the action of dopamine. Dopamine is a messenger substance in the parts of the brain that control movement and co-ordination. In patients with Parkinson's disease, the cells that produce dopamine begin to die and the amount of dopamine in the brain decreases. The patients then lose their ability to control their movements reliably. Leganto delivers a constant supply of rotigotine through the skin into the bloodstream. Rotigotine then stimulates the brain as dopamine would, so that patients can control their movement and have fewer of the signs and symptoms of Parkinson's disease, such as stiffness and slowness of movement. The way rotigotine works in restless legs syndrome is not fully understood. The syndrome is thought to be caused by problems in the way dopamine works in the brain, which may be improved by rotigotine.

How has Leganto been studied?

In Parkinson's disease, Leganto has been compared with placebo (a dummy treatment) in four studies involving 830 patients with early-stage disease and 842 patients with advanced disease. Two of these studies also compared Leganto with other dopamine agonists (ropinirole in early-stage disease and pramipexole in advanced disease). The studies in early-stage disease looked at the number of patients who had at least a 20% improvement in symptoms, as measured with a standard symptom questionnaire. The studies in advanced disease measured the length of time during the day that the patients recorded as 'off' (when they had too many Parkinson's disease symptoms to be able to live normally). Two smaller studies comparing Leganto with ropinirole were completed after the medicine's authorisation.

In moderate to severe restless legs syndrome, Leganto has been compared with placebo in two main studies involving a total of 963 patients. The main measure of effectiveness was the change in symptoms after six months of treatment with a stable dose, measured using two standard scales.

What benefit has Leganto shown during the studies?

Leganto was more effective than placebo in treating Parkinson's disease. In early-stage disease, 48 to 52% of the patients using Leganto had an improvement in symptoms, compared with 19 to 30% of those using placebo. Leganto was less effective than ropinirole: an improvement was seen in 70% of the patients receiving ropinirole. In smaller studies completed later, the effectiveness of Leganto was found to be comparable with ropinirole.

In advanced Parkinson's disease, patients using Leganto had a greater decrease in their 'off' time than those taking placebo (a decrease of 2.1 to 2.7 h with Leganto compared with 0.9 h with placebo). The decrease seen with Leganto was similar to that seen with pramipexole (2.8 h).

In restless legs syndrome, patients using doses of Leganto between 1 and 3 mg/24 h had a greater improvement than those using placebo in the two studies, as measured on both symptom scales.

What is the risk associated with Leganto?

The most common side effects with Leganto in patients with Parkinson's disease (seen in more than 1 patient in 10) are somnolence (sleepiness), dizziness, headache, nausea (feeling sick), vomiting, and application site reactions such as redness, itching and irritation of the skin. In patients with restless legs syndrome, the most common side effects (seen in more than 1 patient in 10) are nausea, application site reactions, asthenic conditions (conditions such as tiredness, weakness and feeling unwell) and headache. For the full list of all side effects reported with Leganto, see the package leaflet.

Leganto must not be used in people who are hypersensitive (allergic) to rotigotine or any of the other ingredients. The backing layer of Leganto contains aluminium. To avoid skin burns, Leganto must be removed if the patient has to have magnetic resonance imaging (MRI) or cardioversion (a process that restores the heart's normal rhythm).

Why has Leganto been approved?

The CHMP decided that Leganto's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Leganto

The European Commission granted a marketing authorisation valid throughout the European Union for Leganto on 16 June 2011.

The full EPAR for Leganto 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 Leganto, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2013.