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EPAR summary for the public

Corbilta

Levodopa / carbidopa / entacapone

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

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

What is Corbilta and what is it used for?

Corbilta is a medicine that contains three active substances: levodopa, carbidopa and entacapone. It is used to treat adults with Parkinson's disease (a progressive brain disorder that causes shaking, slow movement and muscle stiffness).

Corbilta is used in patients who are being treated with a combination of levodopa and an inhibitor of dopa decarboxylase (two standard treatments for Parkinson's disease) but are having 'fluctuations' towards the end of the period between two doses of their medication. Fluctuations happen when the effects of the medication wear off and symptoms re-emerge. They are linked to a reduction in the effect of levodopa, when the patient experiences sudden switches between being 'on' and able to move, and being 'off' and having difficulty moving about. Corbilta is used when these fluctuations cannot be treated with the standard combination alone.

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

How is Corbilta used?

Corbilta is available as a range of tablets in seven strengths, containing 50 to 200 mg levodopa and 12.5 to 50 mg carbidopa. All of the tablets contain 200 mg entacapone. The strength of Corbilta that the patient should use is based on the amount of levodopa they need to control their symptoms. See the summary of product characteristics (also part of the EPAR) for full instructions on how patients should be switched to Corbilta and on how the dose is adjusted during treatment.



The maximum daily dose of Corbilta is 10 tablets, except for the tablets containing 175 mg levodopa and 43.75 mg carbidopa, for which the maximum daily dose is eight tablets, and those containing 200 mg levodopa and 50 mg carbidopa, for which the maximum daily dose is seven tablets.

The medicine can only be obtained with a prescription.

How does Corbilta work?

In patients with Parkinson's disease, the cells in the brain that produce the neurotransmitter dopamine begin to die and the amount of dopamine in the brain decreases. Patients then lose their ability to control their movements reliably. All of the active substances in Corbilta work to restore the levels of dopamine in the parts of the brain that control movement and co-ordination.

Levodopa is converted into dopamine in the brain. Both carbidopa and entacapone block some of the enzymes that are involved in the breakdown of levodopa in the body: carbidopa blocks the enzyme dopa decarboxylase, and entacapone blocks the enzyme catechol-O-methyl transferase (COMT). As a result, levodopa remains active for longer. This helps to improve the symptoms of Parkinson's disease, such as stiffness and slowness of movement.

Entacapone has been authorised in the European Union (EU) as Comtess/Comtan since 1998. The use of combinations of levodopa and carbidopa is well established, having being in use since the mid-1970s. Having all three substances in the same tablet can lower the number of tablets patients have to take and help them stick to their treatment.

What benefits of Corbilta have been shown in studies?

The company used some of the data from Comtess/Comtan (entacapone) to support the use of Corbilta and presented data from the published literature for the use of the combination of levodopa and carbidopa.

The company carried out 'bioequivalence' studies to show that taking Corbilta produces the same levels of levodopa, carbidopa and entacapone in the blood as taking separate tablets containing entacapone and the combination of levodopa and carbidopa.

What are the risks associated with Corbilta?

The most common side effects with Corbilta (seen in more than 1 patient in 10) are dyskinesia (uncontrollable movements), aggravated Parkinsonism (worsening of Parkinson's disease), nausea (feeling sick) and harmless urine discoloration. Serious side effects which have been reported much less often include gastrointestinal haemorrhage (bleeding in the gut) and angioedema (swelling under the skin of face or limbs). For the full list of all side effects reported with Corbilta, see the package leaflet.

Corbilta must not be used in patients with:

- severely reduced liver function;
- narrow-angle glaucoma (increased pressure within the eye);
- phaeochromocytoma (a tumour of the adrenal gland);
- a history of neuroleptic malignant syndrome (a dangerous nervous system disorder usually caused by antipsychotic medicines) or rhabdomyolysis (breakdown of muscle fibres).

Corbilta must not be used together with other medicines that belong to the group 'monoamine oxidase inhibitors' (a type of antidepressant). See the summary of product characteristics (also part of the EPAR) for full details.

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

Why is Corbilta approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Corbilta'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 Corbilta?

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

Other information about Corbilta

The European Commission granted a marketing authorisation valid throughout the European Union for Corbilta on 11 November 2013.

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

This summary was last updated in 10-2014