European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

COMTAN

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 Comtan?
Comtan is a medicine that contains the active substance entacapone. It is available as brown-orange tablets (200 mg).

What is Comtan used for?
Comtan is used to treat patients with Parkinson's disease. Parkinson's disease is a progressive brain disorder that causes shaking, slow movement and muscle stiffness. Comtan is used together with levodopa (either a combination of levodopa and benserazide or a combination of levodopa and carbidopa) when the patient is 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 with a reduction in the effects of levodopa, when the patient experiences sudden switches between being 'on' and able to move, and being 'off' and having difficulties moving about. Comtan is used when these fluctuations cannot be treated with the standard levodopa-containing combination alone.
The medicine can only be obtained with a prescription.

How is Comtan used?
Comtan is only used in combination either with levodopa and benserazide or with levodopa and carbidopa. It is taken as one tablet with each dose of the other medicine, up to a maximum of 10 tablets a day. It can be taken with or without food. When patients first add Comtan to their exiting medication, they may need to take a lower daily dose of levodopa, either by changing how often they take it, or by reducing the amount of levodopa taken in each dose. Comtan can only be used with conventional combinations of levodopa. It should not be used with combinations that are 'modified release' (when the levodopa is released slowly over a few hours).

How does Comtan 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. The patients then lose their ability to control their movements reliably. The active substance in Comtan, entacapone, works to restore the levels of dopamine in the parts of the brain that control movement and co-ordination. It only works when it is taken with levodopa, a copy of the neurotransmitter dopamine that can be taken by mouth. Entacapone blocks an enzyme that is involved in the break down of levodopa in the body called

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

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.

How has Comtan been studied?
Comtan has been studied in a total of 376 patients with Parkinson's disease, in two six-month studies that measured the effects of adding Comtan or placebo (a dummy medicine) to the patient's combination of levodopa and carbidopa or levodopa and benserazide. The main measure of effectiveness was the time spent in the 'on' state (the time when levodopa is controlling the symptoms of Parkinson's disease) after the first levodopa dose of the morning in the first study, and over one day in the second study.

What benefit has Comtan shown during the studies?
Comtan was more effective than placebo in both studies. In the first study, adding Comtan increased the 'on' time by 1 hour and 18 minutes more than adding placebo. In the second study, the 'on' time was increased by 35 minutes compared with placebo.

What is the risk associated with Comtan?
The most common side effects with Comtan (seen in between 1 and 10 patients in 100) are dyskinesia (uncontrollable movements), nausea (feeling sick) and harmless urine discoloration. For the full list of all side effects reported with Comtan, see the Package Leaflet.
Comtan should not be used in people who may be hypersensitive (allergic) to entacapone or any of the other ingredients. Comtan should not be used in patients with:

- liver disease;
- 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).

Comtan should 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.

Why has Comtan been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Comtan's benefits are greater than its risks as an adjunct to standard preparations of levodopa/benserazide or levodopa/carbidopa for use in patients with Parkinson's disease and end-of-dose motor fluctuations, who cannot be stabilised on those combinations. The Committee recommended that Comtan be given marketing authorisation.

Other information about Comtan:
The European Commission granted a marketing authorisation valid throughout the European Union for Comtan to Novartis Europharm Limited on 22 September 1998. The marketing authorisation was renewed on 22 September 2003 and on 22 September 2008.

The full EPAR for Comtan is available here.

This summary was last updated in 08-2008.