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SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Entacapone Orion

entacapone

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

What is Entacapone Orion?

Entacapone Orion is a medicine that contains the active substance entacapone. It is available as tablets (200 mg).

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

What is Entacapone Orion used for?

Entacapone Orion 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. Entacapone Orion 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. Entacapone Orion is used when these fluctuations cannot be treated with the standard levodopa-containing combination alone.

The medicine can only be obtained with a prescription.

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How is Entacapone Orion used?

Entacapone Orion 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 Entacapone Orion to their existing 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. Entacapone Orion 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 Entacapone Orion 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 Entacapone Orion, 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 breakdown of levodopa in the body called 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 Entacapone Orion been studied?

Entacapone Orion has been studied in a total of 376 patients with Parkinson's disease, in two six-month studies that measured the effects of adding Entacapone Orion 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 Entacapone Orion shown during the studies?

Entacapone Orion was more effective than placebo in both studies. In the first study, adding Entacapone Orion 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 Entacapone Orion?

The most common side effects with Entacapone Orion (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 Entacapone Orion, see the package leaflet.

Entacapone Orion should not be used in people who may be hypersensitive (allergic) to entacapone or any of the other ingredients. Entacapone Orion 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).

Entacapone Orion 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 Entacapone Orion been approved?

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

Other information about Entacapone Orion

The European Commission granted a marketing authorisation valid throughout the European Union for Entacapone Orion on 18 August 2011.

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

This summary was last updated in 07-2011.