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EPAR summary for the public

Entacapone Teva

entacapone

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

What is Entacapone Teva?

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

Entacapone Teva is a 'generic medicine'. This means that Entacapone Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Comtess. For more information on generic medicines, see the question-and-answer document here.

What is Entacapone Teva used for?

Entacapone Teva 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 Teva 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 Teva 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 Teva used?

Entacapone Teva 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. When patients first add Entacapone Teva 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 Teva 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 Teva 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 Teva, 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 Teva been studied?

Because Entacapone Teva is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Comtess. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Entacapone Teva?

Because Entacapone Teva is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Entacapone Teva been approved?

The CHMP concluded that, in accordance with EU requirements, Entacapone Teva has been shown to have comparable quality and to be bioequivalent to Comtess. Therefore, the CHMP's view was that, as for Comtess, the benefit outweighs the identified risk. The Committee recommended that Entacapone Teva be given marketing authorisation.

Other information about Entacapone Teva

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

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

The full EPAR for the reference medicine can also be found on the Agency's website.

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