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EPAR summary for the public

Ongentys

opicapone

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

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

What is Ongentys and what is it used for?

Ongentys is a medicine used to treat adults with Parkinson's disease, a progressive brain disorder that causes shaking and muscle stiffness, and slows movement.

Ongentys is used as an add-on to levodopa / DOPA decarboxylase inhibitors (DDCI) (other medicines for Parkinson's disease) in patients who are having fluctuations in the control of their condition. Fluctuations happen when the effects of the medication wear off and symptoms re-emerge before the next dose is due. 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. Ongentys is used when these fluctuations cannot be treated with the standard levodopa-containing combinations alone.

Ongentys contains the active substance opicapone.

How is Ongentys used?

Ongentys is available as capsules (25 mg and 50 mg) to be taken by mouth. The recommended dose is 50 mg, taken once a day at bedtime, at least one hour before or after levodopa combination medicines.

The medicine can only be obtained with a prescription.

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How does Ongentys 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 Ongentys, opicapone, works to restore the levels of dopamine in the parts of the brain that control movement and coordination. It enhances the effects of levodopa, a copy of the neurotransmitter dopamine that can be taken by mouth. Opicapone 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.

What benefits of Ongentys have been shown in studies?

The benefits of Ongentys in Parkinson's disease were investigated in two main studies. In the first study, 600 patients with fluctuations were given Ongentys, entacapone (another medicine for Parkinson's disease) or placebo (a dummy treatment), in addition to their current levodopa / DDCI combination. This study looked at how well the treatments reduced the time when patients have more difficulty moving about, called 'off periods'. After 14-15 weeks, off periods were shortened by 117 minutes (almost 2 hours) in patients taking Ongentys 50 mg, compared with 96 minutes (about 1 and a half hour) in patients taking the comparator medicine entacapone and 56 minutes (less than 1 hour) in patients taking placebo.

In the second study, which also looked at the reduction in off periods, Ongentys was compared with placebo in 427 patients who were taking a levodopa / DDCI combination. After 14-15 weeks, off periods were shortened by 119 minutes (almost 2 hours) in patients taking Ongentys 50 mg, compared with 64 minutes in patients taking placebo.

Both studies were extended for one additional year and confirmed the benefits of Ongentys when used long-term.

In both studies, patients had on average off periods of about 6 to 7 hours at the start of the study.

What are the risks associated with Ongentys?

The most common side effects with Ongentys are disorders of the nervous system (brain and spinal cord). Among these, dyskinesia (difficulty controlling movement) may affect around 2 in 10 people. For the full list of all side effects reported with Ongentys, see the package leaflet.

Ongentys must not be used in:

- patients with tumours of the adrenal glands (small glands located on top of the kidneys) such as pheochromocytoma and paraganglioma;
- patients with a history of neuroleptic malignant syndrome (a nervous system disorder usually caused by antipsychotic medicines) or rhabdomyolysis (breakdown of muscle fibres);
- patients taking medicines known as non-selective monoamine oxidase (MAO) inhibitors except when used to treat Parkinson's disease.

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

Why is Ongentys approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Ongentys's benefits are greater than its risks and recommended that it be approved for use in the EU. Ongentys

was shown to be more effective than placebo and at least as effective as the comparator entacapone in reducing off periods in patients with Parkinson's disease taking levodopa combination medicines. Regarding its safety, Ongentys was considered to be comparable to other medicines of the same class.

What measures are being taken to ensure the safe and effective use of Ongentys?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ongentys have been included in the summary of product characteristics and the package leaflet.

Other information about Ongentys

The European Commission granted a marketing authorisation valid throughout the European Union for Ongentys on 24 June 2016.

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

This summary was last updated in 06-2016.