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EPAR summary for the public

Oprymea

pramipexole

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

What is Oprymea?

Oprymea is a medicine containing the active substance pramipexole. It is available as immediate-release tablets (0.088 mg, 0.18 mg, 0.35 mg, 0.7 mg and 1.1 mg) and prolonged-release tablets (0.26 mg, 0.52 mg, 1.05 mg, 1.57 mg, 2.1 mg, 2.62 mg and 3.15 mg). Immediate–release tablets release the active substance immediately, and prolonged-release tablets release it slowly over a few hours.

Oprymea is a 'generic medicine'. This means that Oprymea is similar to a 'reference medicine' already authorised in the European Union (EU) called Sifrol (also known as Mirapexin). For more information on generic medicines, see the question-and-answer document here.

What is Oprymea used for?

Oprymea is used to treat the symptoms of Parkinson's disease, a progressive brain disorder that causes shaking, slow movement and muscle stiffness. Oprymea can be used either on its own or in combination with levodopa (another medicine for Parkinson's disease), at any stage of disease including the later stages when levodopa starts becoming less effective.

The medicine can only be obtained with a prescription.

How is Oprymea used?

The starting dose is either one 0.088-mg immediate-release tablet three times per day or one 0.26-mg prolonged-release tablet once a day. The dose should be increased every five to seven days until symptoms are controlled without causing side effects that cannot be tolerated. The maximum daily

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dose for the immediate-release tablets is 1.1 mg three times per day and in case of the prolonged release tablets is 3.15 mg once a day. Oprymea must be given less frequently in patients who have problems with their kidneys. If treatment needs to be stopped for any reason, the dose should be decreased gradually.

For more information, see the package leaflet.

How does Oprymea work?

The active substance in Oprymea, pramipexole, is a dopamine agonist, which imitates the action of dopamine. Dopamine is a messenger substance in the parts of the brain that control movement and co-ordination. In patients with Parkinson's disease, the cells that produce dopamine begin to die and the amount of dopamine in the brain decreases. The patients then lose their ability to control their movements reliably. Pramipexole stimulates the brain as dopamine would, so that patients can control their movement and have fewer of the signs and symptoms of Parkinson's disease, such as shaking, stiffness and slowness of movement.

How has Oprymea been studied?

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

What are the benefits and risks of Oprymea?

Because Oprymea is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicine's.

Why has Oprymea been approved?

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

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

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

Other information about Oprymea

The European Commission granted a marketing authorisation valid throughout the EU for Oprymea on 12 September 2008.

The full EPAR for Oprymea 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 Oprymea, 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 EMEA's website.

This summary was last updated in 01-2015.