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Oprymea (*pramipexole*)

An overview of Oprymea and why it is authorised in the EU

What is Oprymea and what is it used for?

Oprymea is a medicine used to treat the symptoms of the following diseases:

- 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;
- moderate to severe restless-legs syndrome, a disorder where the patient has uncontrollable urges to move the limbs to stop uncomfortable, painful or odd sensations in the body, usually at night. Oprymea is used when a specific cause for the disorder cannot be identified.

Oprymea contains the active substance pramipexole.

Oprymea is a 'generic medicine'. This means that Oprymea contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Sifrol (also known as Mirapexin). For more information on generic medicines, see the question-and-answer document here.

How is Oprymea used?

Oprymea can only be obtained with a prescription. 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 into the body immediately, and prolonged-release tablets release it slowly over a few hours.

For Parkinson's disease, the starting dose is either one 0.088 mg immediate-release tablet three times a 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 dose for the immediate-release tablets is 1.1 mg three times a 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.

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For restless-legs syndrome, Oprymea immediate-release tablets should be taken once a day, two to three hours before going to bed. The recommended starting dose is one 0.088 mg tablet, but, if needed, this can be increased every four to seven days to reduce symptoms further, to a maximum of three 0.18 mg tablets. The patient's response and the need for further treatment should be evaluated after three months. The prolonged-release tablets are not suitable for restless-legs syndrome.

Oprymea tablets should be swallowed with water. The prolonged-release tablets must not be chewed, divided or crushed, and should be taken around the same time every day.

For more information about using Oprymea, see the package leaflet or contact your doctor or pharmacist.

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 symptoms of Parkinson's disease, such as shaking, stiffness and slowness of movement.

The way pramipexole works in restless-legs syndrome is not fully understood. The syndrome is thought to be caused by problems in the way dopamine works in the brain, which can be corrected by pramipexole.

How has Oprymea been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Sifrol, and do not need to be repeated for Oprymea.

As for every medicine, the company provided studies on the quality of Oprymea. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Oprymea?

Because Oprymea 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 is Oprymea authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Oprymea has been shown to have comparable quality and to be bioequivalent to Sifrol. Therefore, the Agency's view was that, as for Sifrol, the benefit of Oprymea outweighs the identified risk and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Oprymea are continuously monitored. Side effects reported with Oprymea are carefully evaluated and any necessary action taken to protect patients.

Other information about Oprymea

Oprymea received a marketing authorisation valid throughout the EU on 12 September 2008.

Further information on Oprymea can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. Information on the reference medicine can also be found on the Agency's website.

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