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EPAR summary for the public

Pramipexole Accord

pramipexole

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

What is Pramipexole Accord?

Pramipexole Accord is a medicine that contains the active substance pramipexole. It is available as tablets (0.088, 0.18, 0.35, 0.7 and 1.1 mg).

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

What is Pramipexole Accord used for?

Pramipexole Accord is used to treat the symptoms of Parkinson's disease, a progressive brain disorder that causes shaking, slow movement and muscle stiffness. Pramipexole Accord 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 Pramipexole Accord used?

The starting dose is one 0.088 mg tablet three times 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 is three 1.1 mg tablets. Pramipexole Accord must be given less often in patients who have problems with their kidneys. If treatment is stopped for any reason, the dose should be decreased gradually.

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How does Pramipexole Accord work?

The active substance in Pramipexole Accord, pramipexole, is a dopamine agonist (a substance that 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 Pramipexole Accord been studied?

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

What are the benefits and risks of Pramipexole Accord?

Because Pramipexole Accord 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 Pramipexole Accord been approved?

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

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

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

Other information about Pramipexole Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Pramipexole Accord on 30 September 2011.

The full EPAR for Pramipexole Accord 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 Pramipexole Accord, 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.

This summary was last updated in 06-2016.