European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

PRAMIPEXOLE TEVA

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Pramipexole Teva?

Pramipexole Teva is a medicine containing the active substance pramipexole base. It is available as white, round tablets (0.088, 0.18, 0.35 and 0.7 mg).
Pramipexole Teva is a 'generic medicine'. This means that Pramipexole Teva is similar to a 'reference medicine' already authorised in the European Union (EU) called Sifrol. For more information on generic medicines, see the question-and-answer document here.

What is Pramipexole Teva used for?

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

Pramipexole Teva tablets should be swallowed with water, with or without food. The starting dose is 0.088 mg three times per 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 1.1 mg three times per day. Pramipexole Teva must be given less frequently in patients who have problems with their kidneys. If treatment is stopped for any reason, the dose should be decreased gradually.
For more information, see the Package Leaflet.

How does Pramipexole Teva work?

The active substance in Pramipexole Teva, 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.

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How has Pramipexole Teva been studied?
Because Pramipexole Teva is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine (i.e. that the two medicines produce the same levels of the active substance in the body).

What are the benefit and risk of Pramipexole Teva?
Because Pramipexole Teva is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Pramipexole Teva been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Pramipexole Teva 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 Pramipexole Teva be given marketing authorisation.

Other information about Pramipexole Teva:
The European Commission granted a marketing authorisation valid throughout the EU for Pramipexole Teva to Teva Pharma B.V. on 18 December 2008.

The full EPAR for Pramipexole Teva can be found here.
The full EPAR for the reference medicine can also be found on the EMEA's website.

This summary was last updated in 11-2008.