

Summary Public Assessment Report

Pramipexol Teva Pharma (pramipexole dihydrochloride monohydrate)

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(pramipexole dihydrochloride monohydrate)

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

This is a summary of the public assessment report (PAR) for Pramipexol Teva Pharma. It explains how Pramipexol Teva Pharma was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Pramipexol Teva Pharma.

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

What is Pramipexol Teva Pharma and what is it used for?

Pramipexol Teva Pharma is a ‘generic medicine’. This means that Pramipexol Teva Pharma is similar to a ‘reference medicine’ already authorised in the European Union (EU) called SIFROL.

Pramipexol Teva Pharma is used to treat the symptoms of primary Parkinson’s disease in adults. It can be used alone or in combination with levodopa (another medicine for Parkinson’s disease).

How does Pramipexol Teva Pharma work?

Pramipexol Teva Pharma belongs to a group of medicines known as dopamine agonists, which stimulate dopamine receptors in the brain. Stimulation of the dopamine receptors triggers nerve impulses in the brain that help to control body movements.

How is Pramipexol Teva Pharma used?

The pharmaceutical form of Pramipexol Teva Pharma is prolonged release tablets for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Pramipexol Teva Pharma have been shown in studies?

Because Pramipexol Teva Pharma is a generic medicine, studies in patients have been limited to tests to determine 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 possible side effects of Pramipexol Teva Pharma?

Because Pramipexol Teva Pharma is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Pramipexol Teva Pharma approved?

It was concluded that, in accordance with EU requirements, Pramipexol Teva Pharma has been shown to have comparable quality and to be bioequivalent to the reference medicine SIFROL. Therefore, the Medical Products Agency in Sweden decided that, as for SIFROL, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Pramipexol Teva Pharma?

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

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Pramipexol Teva Pharma

The marketing authorisation for Pramipexol Teva Pharma was granted on 2015-03-19 in Sweden.

The full PAR for Pramipexol Teva Pharma can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Pramipexol Teva Pharma, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2015-03.