LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pramipexol Ferrer (pramipexole)

SE/H/1305/01-07/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Pramipexol Ferrer
(pramipexole)
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 Ferrer. It explains how Pramipexol Ferrer 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 Ferrer.

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

What is Pramipexol Ferrer and what is it used for?

Pramipexol Ferrer is a 'generic medicine'. This means that Pramipexol Ferrer is similar to a 'reference medicine' already authorised in the European Union (EU) called Sifrol.

Pramipexole Ferrer 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 Ferrer work?

Pramipexole Ferrer 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 Ferrer used?

The pharmaceutical form of Pramipexol Ferrer 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 Ferrer have been shown in studies?

Because Pramipexol Ferrer 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 Ferrer?

Because Pramipexol Ferrer 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 Ferrer approved?

It was concluded that, in accordance with EU requirements, Pramipexol Ferrer 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 Ferrer?

A risk management plan has been developed to ensure that Pramipexol Ferrer 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 Ferrer, 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 Ferrer

The marketing authorisation for Pramipexol Ferrer was granted on 2013-08-29 in Sweden.

The full PAR for Pramipexol Ferrer can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Pramipexol Ferrer, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2013-08.