LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Calmolan
(pramipexole)

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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

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Calmolan
(pramipexole)

Prolonged-release tablets

This is a summary of the public assessment report (PAR) for Calmolan. It explains how Calmolan 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 Calmolan.

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

What is Calmolan and what is it used for?

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

Calmolan 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 Calmolan work?

Calmolan contains the active substance pramipexole and 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 Calmolan used?

The pharmaceutical form of Calmolan 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 Calmolan have been shown in studies?

Because Calmolan 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 Calmolan?

Because Calmolan 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 Calmolan approved?

It was concluded that, in accordance with EU requirements, Calmolan 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 Calmolan?

A risk management plan has been developed to ensure that Calmolan 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 Calmolan, 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 Calmolan

The marketing authorisation for Calmolan was granted on 2014-01-16 in Sweden.

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

This summary was last updated in 2014