LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Cromiva
(miglustat)

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Summary Public Assessment Report

Cromiva
(miglustat)

Capsule, hard, 100 mg

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

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

What is Cromiva and what is it used for?

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

Cromiva is used to treat mild to moderate type 1 Gaucher disease in adults.

How does Cromiva work?

In type 1 Gaucher disease, a substance called glucosylceramide is not removed from your body. It starts to build up in certain cells of the body's immune system. This can result in liver and spleen enlargement, changes in the blood, and bone disease.

The usual treatment for type 1 Gaucher disease is enzyme replacement therapy. Cromiva is only used when a patient is considered unsuitable for treatment with enzyme replacement therapy. Miglustat is an inhibitor of the production of glucosylceramide.

How is Cromiva used?

The pharmaceutical form of Cromiva is hard capsule 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 Cromiva have been shown in studies?

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

What are the possible side effects of Cromiva?

Because Cromiva 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 Cromiva approved?

It was concluded that, in accordance with EU requirements, Cromiva has been shown to have comparable quality and to be bioequivalent to the reference medicine Zavesca. Therefore, the Medical Products Agency in Sweden decided that, as for Zavesca, 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 Cromiva?

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

The marketing authorisation for Cromiva was granted on 2014-10-16 in Sweden.

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

This summary was last updated in 2014-10.