

Summary Public Assessment Report

Miglustat Bluefish (miglustat)

SE/H/1358/01/DC

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Capsule, hard, 100 mg

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

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

What is Miglustat Bluefish and what is it used for?

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

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

How does Miglustat Bluefish 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. Miglustat Bluefish 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 Miglustat Bluefish used?

The pharmaceutical form of Miglustat Bluefish 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 Miglustat Bluefish have been shown in studies?

Because Miglustat Bluefish 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 Miglustat Bluefish?

Because Miglustat Bluefish 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 Miglustat Bluefish approved?

It was concluded that, in accordance with EU requirements, Miglustat Bluefish 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 Miglustat Bluefish?

A risk management plan has been developed to ensure that Miglustat Bluefish 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 Miglustat Bluefish, 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 Miglustat Bluefish

The marketing authorisation for Miglustat Bluefish was granted on 2014-10-30 in Sweden.

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

This summary was last updated in 2014-10.