LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ambrisentan Bluefish (ambrisentan)

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Summary Public Assessment Report

Ambrisentan Bluefish
ambrisentan

Film-coated tablet, 5 mg, 10 mg

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

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

What is Ambrisentan Bluefish and what is it used for?

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

Ambrisentan Bluefish is used to treat pulmonary arterial hypertension (PAH) in adults. PAH is high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs. In people with PAH, these arteries get narrower, so the heart has to work harder to pump blood through them. This causes people to feel tired, dizzy and short of breath.

Ambrisentan Bluefish may also be used in combination with other medicines used to treat PAH.

How does Ambrisentan Bluefish work?

Ambrisentan Bluefish widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure and relieves the symptoms.

How is Ambrisentan Bluefish used?

The pharmaceutical form of Ambrisentan Bluefish is film-coated tablet 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 in Sweden.

What benefits of Ambrisentan Bluefish have been shown in studies?

Because Ambrisentan Bluefish is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Volibris.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Ambrisentan Bluefish?
Because Ambrisentan Bluefish is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Ambrisentan Bluefish approved?
It was concluded that, in accordance with EU requirements, Ambrisentan Bluefish has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Volibris. Therefore, the Swedish Medical Products Agency decided that, as for Volibris, the benefits are greater than its risks and recommended that it can be approved for use.

Ambrisentan Bluefish has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Ambrisentan Bluefish?"

What measures are being taken to ensure the safe and effective use of Ambrisentan Bluefish?

A risk management plan has been developed to ensure that Ambrisentan 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 Ambrisentan 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.

Additional risk minimisation measures (including educational material)
This medicine has additional risk minimisation measures for the following risks: Teratogenicity and Hepatotoxicity. The additional risk minimisation measures consist of Educational material for patients (Patient reminder card).

Patient reminder card should include the following key elements:
- That ambrisentan is teratogenic in animals;
- That pregnant women must not take ambrisentan;
- That women of reproductive potential must use effective contraception;
- The need for monthly pregnancy tests;
- The need for regular monitoring of liver function because ambrisentan may cause liver injury.

Other information about Ambrisentan Bluefish

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

This summary was last updated in 2021-MM.
Infoga datum enligt när sPAR blir klar för publicering.