LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Sorafenib Bluefish
(sorafenib tosilate)

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Sorafenib Bluefish
sorafenib tosilate

film-coated tablet, 200 mg

This is a summary of the public assessment report (PAR) for Sorafenib Bluefish. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Sorafenib Bluefish and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Nexavar.

Sorafenib Bluefish is used to treat liver cancer (*hepatocellular carcinoma*).

Sorafenib Bluefish is also used to treat kidney cancer (*advanced renal cell carcinoma*) at an advanced stage when standard therapy has not helped to stop your disease or is considered unsuitable.

How does Sorafenib Bluefish work?

Sorafenib Bluefish is a so-called *multikinase inhibitor*. It works by slowing down the rate of growth of cancer cells and cutting off the blood supply that keeps cancer cells from growing.

How is Sorafenib Bluefish used?

The pharmaceutical form 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 Sorafenib Bluefish have been shown in studies?

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

What are the possible side effects from Sorafenib Bluefish?

Because the product 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 Sorafenib Bluefish approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Nexavar, 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 Sorafenib Bluefish?

A risk management plan has been developed to ensure that the product 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, 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 Sorafenib Bluefish

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

This summary was last updated in 2023-01.