LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Sorafenib Mylan
sorafenib tosilate, sorafenib

SE/H/2271/001

This module reflects the scientific discussion for the approval of Sorafenib Mylan. The Summary Public Assessment Report was written in August 2020 by the previous RMS (NL) after initial procedure NL/H/5057/001/DC. RMS transfer from NL to SE was completed 01-05-2022

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Summary Public Assessment Report

Sorafenib Mylan
sorafenib tosilate, sorafenib

Film-coated tablet, 200 mg

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

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

COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Sorafenib Mylan 200 mg, film-coated tablets

(sorafenib)

NL/H/5057/001/DC

Date: 6 August 2020

COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Sorafenib Mylan 200 mg, film-coated tablets
Active substance: sorafenib

This is a summary of the public assessment report (PAR) for Sorafenib Mylan. It explains how this medicine 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 this medicine.

For practical information about using this medicine, patients should read the package leaflet (PL) or contact their doctor or pharmacist.

What is Sorafenib Mylan and what is it used for?
Sorafenib Mylan is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Nexavar.

This medicine is used to treat liver cancer (hepatocellular carcinoma).
It 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 this medicine work?
The active substance in this medicine, sorafenib, is a protein kinase inhibitor. This means that it blocks some specific enzymes known as protein kinases. These enzymes can be found in some receptors on the surface of cancer cells, where they are involved in the growth and spread of cancer cells, and in the blood vessels that supply the tumours, where they are involved in the development of new blood vessels. By blocking these enzymes, this medicine can reduce the growth of cancer cells and cut off the blood supply that keeps cancer cells growing.

How is this medicine used?
The pharmaceutical form of Sorafenib Mylan is a film-coated tablet and the route of administration is oral. The medicine can only be obtained with a prescription.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because Sorafenib Mylan 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 of this medicine?
Because Sorafenib Mylan 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 all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Nexavar, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Sorafenib Mylan, 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 this medicine
In the Netherlands, the marketing authorisation for Sorafenib Mylan 200 mg was granted on 27 June 2020.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with this medicine, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in August 2020.