LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Mubucho
(dasatinib)

SE/H/2099/01-06/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Mubucho
dasatinib

Film-coated tablet, 16 mg, 40 mg, 55 mg, 63 mg, 79 mg, 111 mg

This is a summary of the public assessment report (PAR) for Mubucho. 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 Mubucho and what is it used for?
The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance but is available as a different strength.

The reference medicine for the product is Sprycel (20 mg, 50 mg, 70 mg, 80 mg, 100 mg, 140 mg).

The company has provided additional own data to demonstrate the safety and efficacy of the product regarding this difference from the reference medicine.

Mubucho contains the active substance dasatinib. This medicine is used to treat chronic myeloid leukaemia (CML) in adults, adolescents and children at least 1 year of age.
Mubucho is also used to treat Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) in adults, adolescents and children at least 1 year of age, and lymphoid blast CML in adults who are not benefiting from prior therapies.

How does Mubucho work?
Leukaemia is a cancer of white blood cells. These white cells usually help the body to fight infection. In people with CML, white cells called granulocytes start growing out of control. Mubucho inhibits the growth of these leukaemic cells.
In people with ALL, white cells called lymphocytes multiply too quickly and live too long. Mubucho inhibits the growth of these leukaemic cells.

How is Mubucho 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 Mubucho have been shown in studies?
Because the product is a hybrid application of Sprycel, clinical studies have been provided for Mubucho to show efficacy for the difference of Mubucho from the reference product Sprycel.

What are the possible side effects from Mubucho?
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 Mubucho approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and similar to the reference medicine. Therefore, the Swedish Medical Products

Agency decided that, as for Sprycel, 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 Mubucho?
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.

Additionally, the company is required to provide educational materials to healthcare professionals.

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

This summary was last updated in 2022-11.