Healthcare Professional Guide
For
Mubucho (dasatinib) film-coated tablets

Purpose of this booklet

This booklet is intended for prescribers and dispensing pharmacists of **Mubucho**. This booklet is part of the marketing authorisation and has been approved by the HPRA. It provides detailed information on posology, impact of pH and drug interactions, and to minimise potential risk of medication error.

Mubucho has a higher bioavailability than other dasatinib-containing products and cannot be used interchangeably with other dasatinib formulations. In case of switch between dasatinib-containing products, the dosing recommendations of the intended product must be followed.

Please instruct the patient about the posology adequately. Please make sure to emphasise Mubucho cannot be switched with other dasatinib-containing products without talking to the doctor. The strength of Mubucho tablets is different from other dasatinib-containing products. This booklet should be read in conjunction with the summary of product characteristics (SmPC).

Version no: 01
Date of HPRA approval: July 2025

1. What is Mubucho?

Mubucho 16 mg, 40 mg, 55 mg, 63 mg, 79 mg and 111 mg film-coated tablets

Therapeutic Indications

Mubucho is indicated for the treatment of **adult** patients with: • Newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase (CML-CP). • Chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including imatinib. • Ph+ acute lymphoblastic leukaemia (ALL) and lymphoid blast CML with resistance or intolerance to prior therapy.
Mubucho is indicated for the treatment of **paediatric** patients with: • Newly diagnosed Ph+ CML in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib. • Newly diagnosed Ph+ ALL in combination with chemotherapy.

2. Posology

Mubucho demonstrates **higher bioavailability** compared to the other dasatinib-containing products. The dose of Mubucho have been **reduced by 21%** compared to other dasatinib products to achieve similar exposure.

In case of switch between dasatinib-containing products, the dosing recommendations of the intended product must be followed.

Recommended doses of Mubucho in case of switching from other dasatinib-containing products:

Mubucho (mg)	Other dasatinib-containing products. (mg)
16	20
40	50
55	70
63	80
79	100
111	140

Adult patients

Dosage of Mubucho film-coated tablets for adult patients:

Indication	The recommended starting dose of Mubucho
CML-CP	79 mg once daily
Accelerated, myeloid or lymphoid blast phase (advanced phase) CML or Ph+ ALL	111 mg once daily

Dose increase or reduction is recommended based on patient response and tolerability.

Paediatric population (Ph+ CML-CP and Ph+ ALL)

Dosing for children and adolescents is on the basis of body weight.

Dosage of Mubucho film-coated tablets for paediatric patients with Ph+ CML-CP or Ph+ ALL:

Body weight (kg)[a]	Mubucho daily dose (mg)
10 to < 20	32
20 to < 30	48
30 to < 45	55
≥ 45	79

[a] *Mubucho film-coated is not recommended for patients weighing less than 10 kg; dasatinib powder for oral suspension should be used for these patients.*

Recalculate the dose every 3 months based on changes in body weight, or more often if necessary.
Dose increase or reduction is recommended based on individual patient response and tolerability.
There is no experience with dasatinib treatment in children under 1 year of age.

Administer once daily.

Mubucho has a higher bioavailability than other dasatinib-containing products and cannot be used interchangeably with other dasatinib formulations. In case of switch between dasatinib-containing products, the dosing recommendations of the intended product must be followed.

For the details on dose escalation and dose adjustment for adverse reactions, please see the SmPC.

3. Decreased gastric acidity

In patients receiving Mubucho, the **dasatinib plasma concentrations may be influenced by gastric pH.**

Pharmacokinetic data have shown that an acidic environment is required for release of the active drug from the product, hence absorption may be reduced:

- in patients with achlorhydria/hypochlorhydria/decreased gastric acidity. Dose adjustments may be necessary in such situations,
- after the use of certain drugs (antacid drugs, histamine H_2 antagonists, proton pump inhibitors),
- in certain disease states (e.g. atrophic gastritis, pernicious anaemia, chronic Helicobacter pylori infection),
- and after surgery (vagotomy, gastrectomy).

The pH dependency should be taken into account when changing dasatinib formulation (e.g. the plasma dasatinib concentration may decrease after changing from Mubucho to other dasatinib formulations in patients with a high gastric pH).

Please also refer to following sections of interactions (with H2-antagonists, PPIs and antacids).

4. Interactions with histamine-2 antagonists and proton pump inhibitors

In order to minimise the impact of reduction of exposure to dasatinib, **H_2 antagonists and proton pump inhibitors are recommended to be taken as a single daily dose 2 hours following the administration of Mubucho.**

5. Interactions with antacids

Antacids such as aluminium hydroxide / magnesium hydroxide products should be administered up to 2 hours prior to, or 2 hours following the administration of Mubucho.

6. Information for the patient

Please instruct the patient:

- Do not switch between taking Mubucho tablets and other dasatinib-tablets without talking to your doctor.
- The strength of Mubucho tablets is different from other dasatinib-containing medicines.

7. Reporting suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance www.hpra.ie.

8. Further information

Adverse events should also be reported to Zentiva k.s. Medical Information via telephone on +353 818 882 243 or via e-mail at PV-Ireland@zentiva.com.