ZENTIVA

PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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

IMPORTANT: RISK MINIMISATION MATERIALS on posology, impact of pH and drug interactions, and to minimise potential risk of medication error.

Dear Healthcare professional,

Zentiva k.s would like to inform you that, in accordance with the conditions of the Marketing Authorisation, risk minimisation materials are available for healthcare professionals who may prescribe or dispense Mubucho Zentiva.

These materials are designed to provide detailed information on posology, impact of pH and drug interactions, and to minimise potential risk of medication error.

The educational package includes:

- **HCP guide**

  Key topics covered:
  Description of Mubucho formulation and differences from other dasatinib formulation.
  - The information that Mubucho cannot be used interchangeably with other dasatinib formulations.
  - The recommended posology of the product. Information about reduction of the dose by 21 % compared to other dasatinib products to achieve similar exposure.
  - Impact of pH
  - Information that dose adjustments might be necessary in patients with achlorhydria/hypochlorhydria/decreased gastric acidity
  - Information on drug interactions (histamine-2 antagonists, proton pump inhibitors, Antacids)
  - Information on timely administration of histamine-2-antagonists, proton pump inhibitors and aluminium hydroxide/magnesium hydroxide

Please ensure all relevant clinical staff are made aware of these materials and that they communicate the necessary information to patients.

A copy of the HCP guide is included with this letter. Further hard copies are available upon request.

For electronic access to the non-promotional educational and support materials for HCPs and patients, please refer to https://www.hpra.ie/ or https://www.medicines.ie/ or printed copies

are also available upon request from the Zentiva k.s. Medical Information via telephone on +353 818 882 243 or via e-mail at PV-Ireland@zentiva.com.

Please refer to the Mubocho Summary of Product Characteristics at https://www.hpra.ie/ or https://www.medicines.ie/ before prescribing.

Reporting of side effects:
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.

Adverse events may 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. When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Yours faithfully,

Signed by:
Janet Lewis
Signer Name: Janet Lewis
Signing Reason: I approve this document
Signing Time: 17-Jul-2025 | 16:08 CEST
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Janet Lewis
Head of Scientific Affairs

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