DASATINIB (reliable absorption) Film-coated Tablets

Can be taken by all patients irrespective of stomach pH

- **Indicated for:**
  - Newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in the chronic phase.
  - Chronic,accelerated, or blast phase CML with resistance or intolerance to prior therapy, including Imatinib.
  - Ph+ acute lymphoblastic leukemia (ALL) and lymphoid blast CML with resistance or intolerance to prior therapy.
- **Posology:** Can be taken two hours after PPI administration.

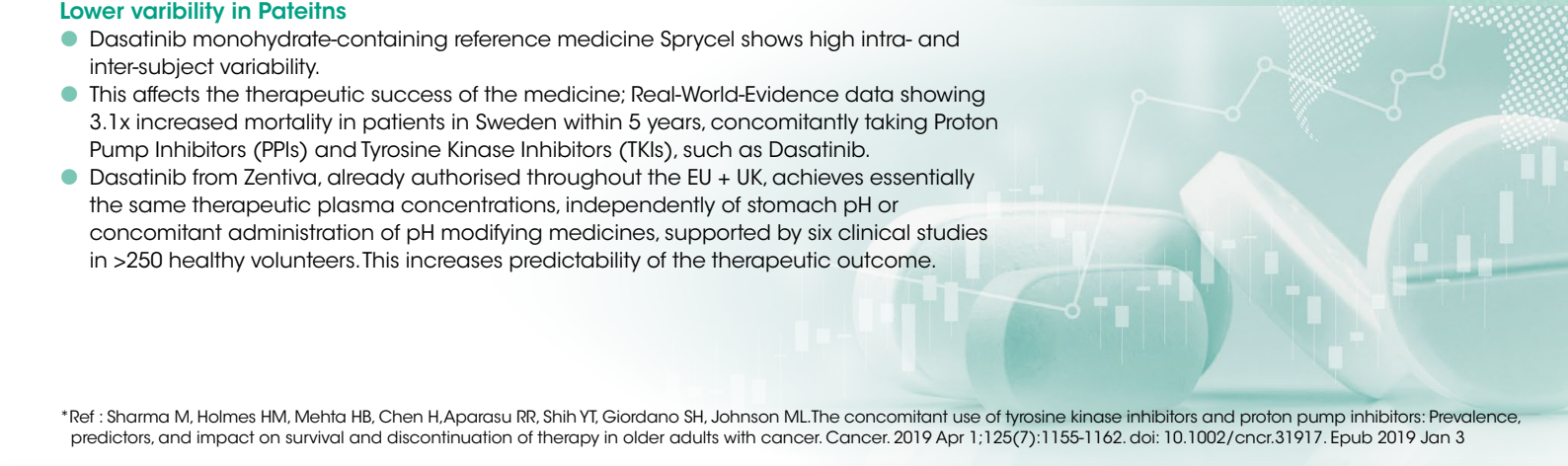
Reliability: Physicians can rely on the product's absorption

Available strengths: 15.8, 39.5, 55.3, 63.2, 79 and 110.6mg

Supra bioavailable: Lower impact to environment

Lower varibility in Pateitns

- Dasatinib monohydrate-containing reference medicine Sprycel shows high intra- and inter-subject variability.
- This affects the therapeutic success of the medicine; Real-World-Evidence data showing 3.1x increased mortality in patients in Sweden within 5 years, concomitantly taking Proton Pump Inhibitors (PPIs) and Tyrosine Kinase Inhibitors (TKIs), such as Dasatinib.
- Dasatinib from Zentiva, already authorised throughout the EU + UK, achieves essentially the same therapeutic plasma concentrations, independently of stomach pH or concomitant administration of pH modifying medicines, supported by six clinical studies in >250 healthy volunteers.This increases predictability of the therapeutic outcome.



*Ref : Sharma M, Holmes HM, Mehta HB, Chen H,Aparasu RR, Shih YT, Giordano SH, Johnson ML.The concomitant use of tyrosine kinase inhibitors and proton pump inhibitors: Prevalence, predictors, and impact on survival and discontinuation of therapy in older adults with cancer. Cancer. 2019 Apr 1;125(7):1155-1162. doi: 10.1002/cncr.31917. Epub 2019 Jan 3

Intellectual property

- Priority patent application covering the unique formulation filed

Regulatory pathway

- UK approval 11/2021
- EU DCP procedure finished in 05/2022
- Reference medicinal product: SPRYCEL, from Bristol-Myers Squibb Pharma EEIG, 20, 50, 70, 80, 100, 140mg, FCT
- Legal basis: Article 10(3) hybrid application for all strengths

Development status

- The EU dossier has been approved.
- The US FDA scientific advice has been finalized

Partnership options

- The product is available for out-licensing in select European markets
- US and RoW available

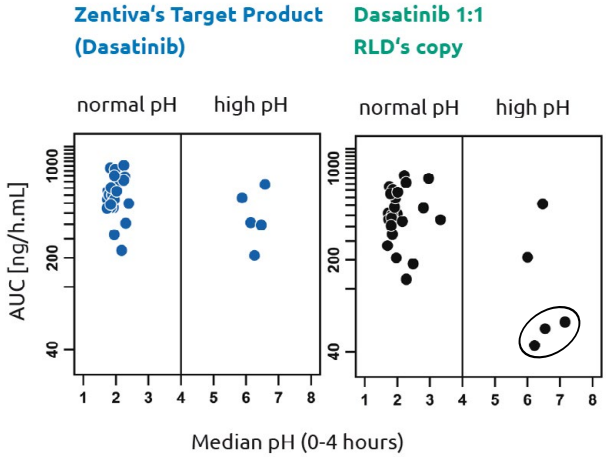


FIG. Randomized, open-label, single-dose, comparative bioavailability study of Dasatinib 140mg, film-coated tablet versus Sprycel 140mg, film-coated tablets, in healthy volunteers under fasting conditions

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