



NILOTINIB (food independence) Tablets

- **Indicated for:**

- Adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase
- Adult and paediatric patients with chronic and accelerated phase Philadelphia chromosome positive CML with resistance or intolerance to prior therapy including Imatinib

- **Posology:** Twice daily with or without food

Available strengths: equivalent to 100mg and 200mg of Tasigna

- Due to twice daily dosing, there is a 6-h period during the day where the patients cannot eat. If food is inappropriately consumed, the increased systemic exposure (AUC) and C_{max} could contribute to prolongation of the QT interval and have potential fatal consequences in patients
- The Nilotinib NFE tablet formulations have been designed to potentially allow for a dose reduction and to reduce the food effect compared to RLD. Thus the safety risk for the patients can be eliminated in this respect

Safer treatment options
- lower risk of overdose
and related side effects
such as prolongation
of the QT interval

Improved compliance
- less limiting food
restrictions

Supra bioavailable
- lower environmental
waste



Intellectual property

- Priority patent application for NFE formulations filed December 2020

Regulatory pathway

- Reference medicinal product: Tasigna 50, 150 and 200mg, hard gelatin capsules from Novartis
- Legal basis: expected Article 10(3) hybrid application for all strengths

Development status

- Pilot bio-equivalency study for proof of concept available from Q4/2022
- Pivotal bio-equivalency study in Q4/2023
- EU dossier available from Q1/2024

Partnership options

- Product is available for out-licensing in selected markets in Europe
- Dossier can be adjusted to markets outside Europe based on request

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