



14 September 2017  
EMA/CHMP/600427/2017  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Imatinib Teva B.V.

#### imatinib

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Imatinib Teva B.V., intended for the treatment of leukaemia and gastrointestinal stromal tumours. The applicant for this medicinal product is Teva B.V.

Imatinib Teva B.V. will be available as capsules and film-coated tablets (100 mg and 400 mg). The active substance of Imatinib Teva B.V. is imatinib, a protein kinase inhibitor that potently inhibits the activity of the Bcr-Abl tyrosine kinase (TK), as well as several receptor TKs (ATC code: L01XE01).

Imatinib Teva B.V. is a generic of Glivec, which has been authorised in the EU since 7 November 2001. Studies have demonstrated the satisfactory quality of Imatinib Teva B.V. and its bioequivalence to the reference product Glivec. A question and answer document on generic medicines can be found [here](#).

The full indication is:

“Imatinib Teva B.V. is indicated for the treatment of

- Paediatric patients with newly diagnosed Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML) for whom bone marrow transplantation is not considered as the first line of treatment.
- Paediatric patients with Ph+ CML in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis.
- Adult patients with Ph+ CML in blast crisis.
- Adult and paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy.
- Adult patients with relapsed or refractory Ph+ ALL as monotherapy.
- Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



- Adult patients with advanced hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRa rearrangement.

The effect of imatinib on the outcome of bone marrow transplantation has not been determined.

Imatinib Teva B.V. is indicated for

- The treatment of adult patients with Kit (CD 117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST).
- The adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive GIST. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment.
- The treatment of adult patients with unresectable dermatofibrosarcoma protuberans (DFSP) and adult patients with recurrent and/or metastatic DFSP who are not eligible for surgery.

In adult and paediatric patients, the effectiveness of imatinib is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on haematological response rates in HES/CEL and on objective response rates in adult patients with unresectable and/or metastatic GIST and DFSP and on recurrence-free survival in adjuvant GIST. The experience with imatinib in patients with MDS/MPD associated with PDGFR gene re-arrangements is very limited (see section 5.1). There are no controlled trials demonstrating a clinical benefit or increased survival for these diseases.”

It is proposed that Imatinib Teva be prescribed by physicians experienced in the treatment of patients with haematological malignancies and malignant sarcomas.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.