18 October 2012
EMA/CHMP/597641/2012
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Imatinib Teva

imatinib

On 18 October 2012 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 film-coated tablet 100mg and 400mg and Imatinib Teva capsules 100mg and 400mg intended for the treatment of leukaemia. The applicant for this medicinal product is Teva Pharma B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Imatinib Teva is imatinib, a protein kinase inhibitor, ATC code: L01XE01.

It is a small molecule protein-tyrosine kinase inhibitor that potently inhibits the activity of the Bcr-Abl tyrosine kinase (TK), as well as several receptor TKs.

Imatinib Teva 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, and its bioequivalence with the reference product Glivec. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Imatinib Teva will be implemented as part of the marketing authorisation.

The approved indication is:

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.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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

In adult and paediatric patients, the effectiveness of imatinib is based on overall haematological and cytogenetic response rates and progression-free survival in CML.

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

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 will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Imatinib Teva and therefore recommends the granting of the marketing authorisation.