2 August 2013
EMA/CHMP/443409/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Imatinib medac

imatinib

On 2 August 2013 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 medac, hard capsules 100mg and 400 mg intended for the treatment of leukaemia.

The applicant for this medicinal product is medac Gesellschaft fuer Spezialpraeparaten mbH. 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 medac is imatinib, a protein kinase inhibitor, ATC code: L01XE01.

Imatinib medac is a generic of Glivec, which has been authorised in the EU since 7 November 2001. Studies have demonstrated the satisfactory quality of Imatinib medac 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 medac will be implemented as part of the marketing authorisation.

The approved indications are:

- 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.
- Adult and paediatric patients with Ph+ CML in blast crisis.
- Adult 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.

[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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- Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements.
- Adult patients with advanced hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangement.
- Adult patients with unresectable dermatofibrosarcoma protuberans (DFSP) and adult patients with recurrent and/or metastatic DFSP who are not eligible for surgery

The effect of Imatinib medac 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 medac 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 medac and therefore recommends the granting of the marketing authorisation.