EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 February 2013
EMA/CHMP/82403/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Imatinib Actavis

Imatinib

On 21 February 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 Actavis, 50 mg and 100 mg hard capsule and 100 mg 400 mg Film-coated tablet intended 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.

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.

The applicant for this medicinal product is Actavis Group PTC ehf. 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 Actavis 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 Actavis is a generic of Glivec, which has been authorised in the EU since 7 November 2001. Studies have demonstrated the satisfactory quality of Imatinib Actavis, and its bioequivalence with the reference product Glivec. A question and answer document on generic medicines can be found here.

[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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An agency of the European Union

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

The approved indication is: “Imatinib Actavis 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.

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 Actavis 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 Actavis and therefore recommends the granting of the marketing authorisation.