



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Imbruvica

ibrutinib

On 24 July 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Imbruvica 140 mg hard capsule intended for the treatment of relapsed or refractory mantle cell lymphoma (MCL) and chronic lymphocytic leukaemia (CLL).

Imbruvica was designated as an orphan medicinal product on 26 April 2012 for treatment of MCL and on 12 March 2013 for treatment of CLL.

The applicant for this medicinal product is Janssen–Cilag International NV. 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 Imbruvica is ibrutinib, an antineoplastic agent (ATC code: L01XE27) which inhibits Bruton's tyrosine kinase, a signalling molecule of the B-cell antigen receptor (BCR) and cytokine receptor pathways.

The benefits in CLL of Imbruvica are in terms of improved progression free survival (PFS) as shown in a randomised controlled trial against ofatumumab. The benefits in MCL of Imbruvica are in terms of overall response rate and duration of response as shown in a single-arm study. The most common side effects are: pneumonia, upper respiratory tract infection, sinusitis, neutropenia, thrombocytopenia, anaemia, dizziness, headache, haemorrhage, bruising, petechiae, diarrhoea, vomiting, stomatitis, nausea, constipation, rash, arthralgia, musculoskeletal pain, pyrexia and peripheral oedema.

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

The approved indication is:

" Imbruvica is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

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.



Imbruvica is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.”

It is proposed that Imbruvica be initiated and supervised by a physician experienced in the use of anticancer medicinal products.

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.

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