22 January 2015
EMA/CHMP/197/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Raplixa

human fibrinogen/human thrombin

On 22 January 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Raplixa, 79 mg/g, 726 IU/g, sealant powder intended as supportive treatment in adults where standard surgical techniques are insufficient for improvement of haemostasis. The applicant for this medicinal product is ProFibrix BV. 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 Raplixa is human plasma–derived fibrinogen and thrombin powder, a local haemostatic (B02BC30), which acts by promoting the physiological blood coagulation through conversion of fibrinogen to fibrin and subsequent fibrin clot formation by the clotting cascade.

The benefit with Raplixa is its ability to reduce the time to haemostasis compared to using a gelatin sponge alone as seen in clinical studies in patients undergoing spinal, vascular, liver and soft tissue surgery where conventional surgical techniques such as suture, ligature and cautery were ineffective or impractical. The most common side effects are insomnia and pruritus.

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

The approved indication is: "Supportive treatment where standard surgical techniques are insufficient for improvement of haemostasis. Raplixa must be used in combination with an approved gelatin sponge. Raplixa is indicated in adults over 18 years of age." It is proposed that the use of Raplixa should be restricted to experienced surgeons.

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 Raplixa and therefore recommends the granting of the marketing authorisation.

[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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