European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 July 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
EVICEL

Common Names: ***human fibrinogen and human thrombin***

On 24 July 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Evicel consisting of two components, Human Fibrinogen 50-90 mg/ml and Human Thrombin 800-1200 IU/ml, solutions for sealant intended for use as supportive treatment in surgery. The applicant for this medicinal product is Omrix Biopharmaceuticals S.A..

The active substances of Evicel, a local haemostatic medicinal product (ATC code: B02BC), are Human Fibrinogen and Human Thrombin purified from human plasma. The reaction of fibrinogen with thrombin initiates the last phase of physiological blood coagulation. Fibrinogen is converted by thrombin into fibrin monomers which spontaneously polymerise to a fibrin clot. The fibrin is then cross linked by endogenous blood clotting factor XIII, creating a firm, mechanically stable network with good adhesive properties.

The benefits with Evicel have been demonstrated in terms of absence of bleedings at the target site in two randomised controlled clinical trials, one in haemostasis and suture support in patients undergoing vascular surgery compared to manual compression and a second one in patients undergoing retroperitoneal and intra-abdominal surgery compared to the haemostatic agent Surgicel. The most common side effects in vascular surgery are graft infection and staphylococcal infection, haematoma, oedema peripheral, decreased haemoglobin, and injury or procedural complications (incision site haemorrhage, vascular graft occlusion, wound, post-procedural haematoma and post-operative wound complication). In retroperitoneal and intra-abdominal surgery the most common side effect is abdominal abscess.

A pharmacovigilance plan for Evicel, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Evicel is used as supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis. Evicel is also indicated as suture support for haemostasis in vascular surgery". It is proposed that the use of Evicel is restricted to experienced surgeons.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) 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 that there is a favourable benefit to risk balance for Evicel and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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