EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends new advice to surgeons on safer use of fibrin sealants Evicel and Quixil

New measures to minimise the risk of gas embolism during spray application

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended a number of risk-minimisation measures for the fibrin sealants Evicel and Quixil to minimise the risk of gas embolism when these medicines are applied as spray during surgery.

Fibrin sealants are used in a wide range of surgical procedures to help reduce local bleeding. They can be applied by dripping or spraying the solution onto bleeding tissue, where they form a fibrin clot, stopping bleeding and thereby helping the wound to heal. The solution is currently sprayed using either pressurised air or carbon dioxide (CO_2).

The review of these medicines was initiated following reports of gas embolism occurring in association with the use of spray devices that use a pressure regulator to administer these medicines. These events appear to be related to the use of the spray device at higher-than-recommended pressures and/or in closer-than-recommended proximity to the tissue surface.

Following review of all available information, the CHMP concluded that the existing instructions for healthcare professionals on the use of these medicines were not sufficient to minimise the risk of this rare but life-threatening adverse effect. The Committee therefore recommended a number of new risk-minimisation measures to ensure correct use of these medicines when applied as a spray. Specifically, the Committee recommended that:

- Evicel and Quixil should be sprayed using CO_2 only, instead of pressurised air, because the greater solubility of CO_2 in blood reduces the risk of embolism;
- the product information of these medicines should be updated with clear and consistent advice for healthcare professionals regarding recommended pressure and distance to use during spraying application;
- these medicines should not be sprayed in endoscopic surgery; when used in laparoscopic (abdominal) surgery, care should be taken to ensure that the minimum safe distance from tissue is observed;

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- the marketing authorisation-holder for Evicel and Quixil should ensure that these products are used with pressure regulators that do not exceed the maximum pressure required to deliver the fibrin sealant, and that they contain labels stating the recommended pressure and distance.

Healthcare professionals in the European Union (EU) will receive a letter explaining these new risk-minimisation measures. In addition, they will also receive new educational material, which the marketing-authorisation holder for Evicel and Quixil has committed to develop as a follow-up to this safety review.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Evicel is the only centrally authorised fibrin sealant. It was authorised in October 2008 and is available in Austria, Denmark, Estonia, Finland, France, Germany, Ireland, the Netherlands, Spain, Sweden, the UK and Norway. The marketing-authorisation holder for Evicel is Omrix biopharmaceuticals S.A.
3. Quixil is a nationally authorised medicine. The marketing-authorisation holder is voluntarily withdrawing Quixil from the European market and replacing it by Evicel.
4. The CHMP is also reviewing four other fibrin sealants marketed in the EU: Tisseel, Tissucol, Artiss and Beriplast P (and associated names). The review for these medicines is still ongoing.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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