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EPAR summary for the public

Raplixa

human fibrinogen / human thrombin

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This is a summary of the European public assessment report (EPAR) for Raplixa. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Raplixa.

For practical information about using Raplixa, patients should read the package leaflet or contact their doctor or pharmacist.

What is Raplixa and what is it used for?

Raplixa is a medicine used in adults to help stop bleeding during surgery when standard surgical methods for controlling bleeding, such as stitches, are insufficient.

Raplixa contains human fibrinogen and human thrombin as active substances. It must be used with an approved type of sponge made of gelatin.

How is Raplixa used?

Raplixa should only be used by experienced surgeons and it can only be obtained with a prescription.

Raplixa is available as a powder (0.5, 1 and 2 grams). The amount of Raplixa to be supplied and the frequency of application depend on patient's need and factors such as the type or surgery, size of the wound and severity of bleeding. A thin layer of the powder can be applied directly from the vial or using a spray device directly onto the bleeding surface, followed by application of the gelatin sponge. The powder can also be applied onto the moistened gelatin sponge, which is immediately applied onto the bleeding surface. For further information, see the Summary of Product Characteristics.

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How does Raplixa work?

The active substances in Raplixa, human fibrinogen and human thrombin, are natural proteins in the blood and are obtained from blood donors. When applied to a moist surface, the thrombin is activated and cuts fibrinogen up into smaller units called fibrin. The fibrin then aggregates (sticks together) and forms a fibrin clot that holds the gelatin sponge tightly to the wound surface, preventing bleeding and sealing the tissue. The sponge is left in the body, where it dissolves and disappears completely.

What benefits of Raplixa have been shown in studies?

Raplixa has been shown to be effective in helping to stop bleeding during surgeries in one main study involving 721 patients undergoing surgeries of the spine, liver, blood vessels or soft tissue, and who had mild or moderate bleeding that could not be controlled by standard techniques. The study compared Raplixa used with the gelatin sponge, with the gelatin sponge used on its own. Across all surgery types, patients in the Raplixa group had their bleeding stopped within 1 to 2 minutes compared with 2 to 4 minutes for patients in the control group. On average, using Raplixa reduced the bleeding time by about 2 minutes.

What are the risks associated with Raplixa?

The most common side effects with Raplixa (which may affect up to 1 in 10 people) are insomnia (difficulty sleeping) and pruritus (itching). Other rarely observed side effects with this type of medicine may include allergic reactions.

Air or gas embolism (air or gas bubbles in the blood that affect the blood flow), which can be life threatening, has occurred with the use of other spray devices to administer fibrin. A very low risk cannot be totally excluded with Raplixa. For the full list of all side effects reported with Raplixa, see the package leaflet.

Raplixa must not be applied intravascularly (to the inside of blood vessels); it must not be applied as a spray during endoscopy (a procedure that uses a tube with a camera for viewing the inside of the body) or during laparoscopy (a keyhole surgery that allows the surgeon to operate without making a large cut in the body) and must not be used as a glue to fix patches or as a glue in the gut to bring together distant parts of the gut (gastrointestinal anastomoses). It must also not be used to treat severe bleeding from the arteries. For the full list of restrictions, see the package leaflet.

Why is Raplixa approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Raplixa's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee considered that Raplixa is effective at reducing the time to stop mild or moderate bleeding during surgery when standard surgical techniques, such as stitches, are insufficient. Raplixa is formulated as a powder in vials which can be stored at room temperature, and once opened it can be used within two hours, which allows for it to be used on multiple bleeding sites. Safety was considered acceptable, provided agreed measures were followed.

What measures are being taken to ensure the safe and effective use of Raplixa?

A risk management plan has been developed to ensure that Raplixa is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and

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the package leaflet for Raplixa, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Raplixa will ensure that all surgeons using Raplixa are provided with educational material to inform them of the risk of air or gas embolism and how to use the spray correctly.

Further information can be found in the summary of the risk management plan.

Other information about Raplixa

The European Commission granted a marketing authorisation valid throughout the European Union for Raplixa on 19 March 2015.

The full EPAR and risk management plan summary for Raplixa can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Raplixa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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