Package leaflet: information for the user

BioTrombina 400

Thrombinum bovine

Powder and solvent for solution for topical use 400 IU, 200 IU/mL

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What BioTrombina 400 is and what it is used for

Bovine thrombin is a proteolytic enzyme catalysing the blood coagulation process. It is involved in the final phase of the coagulation process during conversion of fibrinogen into fibrin and clot formation. BioTrombina 400 administered appropriately and in the right dose allows to control bleeding within few minutes, even in patients with various types of bleeding diasthesis (except for fibrin deficiency) involving impairment of prothrombin conversion into active thrombin (e.g. haemophilia A and haemophilia B).

BioTrombina 400 is indicated for the inhibition of local heavy bleeding from:
- Internal organs (liver, kidneys, lungs) during surgical procedures,
- dental alveolus after tooth extraction,
- nose, mucous membrane of oral cavity, after tonsillectomy,
- the genital tract during gynaecological procedures.

2. What you need to know before you use BioTrombina 400

Do not use BioTrombina 400

- if you are allergic to bovine protein or to any of the other ingredients of this medicine (listed in section 6).
- if bleeding occurs from big blood vessels
- if the wound is infected

Warnings and precautions

Take special care with BioTrombina 400, if:
- you were treated with medicines containing bovine thrombin or any other bovine protein, due to the risk of allergic reaction or haemorrhagic complication,
- you have afibrinogenemia and dysfibrinogenaemia, due to decreased or lack of effectiveness of the medicine.

Other medicines and BioTrombina 400
Never take BioTrombina 400 together with thrombolytic drugs and thrombin inhibitors.
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
No sufficient data concerning using BioTrombina 400 during pregnancy and breast-feeding is available. You should consider benefits and potential risk after using the medicine.

Driving and using machines
BioTrombina 400 has no influence on the ability to drive and use machines.

3. How to use BioTrombina 400

BioTrombina 400 should never be administered intravenously.

Dosage is determined by a physician depending on bleeding intensity.
Powder in an ampoule or vial reconstitute in 2 ml of the solvent (isotonic solution of sodium chloride). After reconstitution, soak a sterile tampon or spongostan with the solution and apply on the wound or apply the solution directly on the wound.

If you use more BioTrombina 400 than you should
No data concerning drug overdose is available

4. Possible side effects

Like all medicines, BioTrombina 400 can cause side effects.
Bovine thrombin is a protein and may trigger production of antibodies which after re-administration of the medicine may cause allergic reactions and bleeding of different intensity.

Your blood antibody level may rise after every subsequent application of product with bovine thrombin. In rare cases, produced antibodies may trigger allergic reactions, including anaphylaxis. Side effects may include urticaria, itching of lips, tongue, palate, breathing problems related to swelling of the oral cavity, tongue; wheezing; hypotension, fainting, systemic urticaria, pruritus, vomiting.

In any case, proper treatment should be applied.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Pharmacovigilance Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:
Al. Jerozolimskie 181C, 02-222 Warszawa, Phone: 22 49-21-301, fax: 22 49-21-309, email: ndl@urpl.gov.pl.
Adverse reactions can be also reported to the marketing authorization holder.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store BioTrombina 400

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton.
Thrombin reconstituted in the solvent (isotonic solution of sodium chloride) is not stable, it gets partially inactivated and therefore should be used immediately after dissolving the powder.
Batch number (Lot)
Expiry date (EXP)

6. Contents of the pack and other information

What BioTrombina 400 contains
One ampoule or vial with powder contains
Bovine thrombin 400 IU
Excipients: glycine

1 mL of the solution (after reconstitution in 2 mL of solvent) contains:
Bovine thrombin 200 IU
Excipients: glycine, sodium chloride, water for injections.

One 2 mL ampoule with the solvent (isotonic solution of sodium chloride) contains: sodium chloride, water for injections.

What BioTrombina 400 looks like and contents of the pack

What BioTrombina 400 looks like

The powder is homogenous, it constitutes a compact dry mass of white or light-beige colouring.
The solvent is colourless.

The packaging

1 vial of powder with 400 IU and 1 ampoule with 2 mL of solvent
5 vials of powder with 400 IU and 5 ampoules with 2 mL of solvent
5 ampoules of powder with 400 IU and 5 ampoules with 2 mL of solvent

Marketing Authorisation Holder and Manufacturer
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