APPROVED
By Marlienka at 9:38 am, Aug 02, 2021

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

Haemostop 500 mg/5 mL Injection

Tranexamic acid

Sugar free

Read all of this leaflet carefully before you are given Haemostop

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What Haemostop is and what it is used for

2. What you need to know before you are given Haemostop

3. How to use Haemostop

4. Possible side effects

5. How to store Haemostop

6. Contents of the pack and other information

1. What Haemostop is and what it is used for

Haemostop contains tranexamic acid which belongs to a group of medicines called antihaemorragics; antifibrinolitics, amino acids.

Haemostop is used in adults and children above one year of age for the prevention and treatment of bleeding due to a process that inhibits blood clotting called fibrinolysis.

Specific indications include:

- Bleeding in the eye (hyphaema).
- In the treatment of patients with established coagulopathies (the inability of blood to clot) who are undergoing minor surgery.
- Management of dental extractions in haemophiliacs (people with a tendency to uncontrolled bleeding).
- Inherited blood disorder that causes attacks of swelling that may affect the face, extremities, genitals, gastrointestinal tract and upper airways.
- Heavy periods in women.

2. What you need to know before you are given Haemostop

Haemostop should not be administered to you:

- if you are hypersensitive (allergic) to tranexamic acid or to any other ingredients of Haemostop (listed in section 6).
- in cases of massive upper urinary tract bleeding.
- if you have a tendency to form blood clots.
- if you have a condition called 'consumption coagulopathy' where blood in the whole body starts to clot.
- if you have a history of convulsions.
- by injection into the spinal cord (intrathecal injection) or brain (intraventricular injection).
- if you have a vision disorder.
- if you have blood clots in one or more veins (thrombophlebitis).
- if you have impaired liver function.
- if you have bleeding in the area between the brain and the tissues that cover the brain (subarachnoid bleeding).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with Haemostop:

- if you have had convulsions, Haemostop should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with Haemostop.
- if you are on a long-term treatment with Haemostop, attention should be paid to possible disturbances of colour vision and if necessary, the treatment should be discontinued. With continuous long-term use of Haemostop, regular ophthalmologic examinations (eye examinations including visual acuity, colour vision, fundus, visual field etc.) are indicated. With pathological ophthalmic changes, particularly with diseases of the retina, your doctor must take a decision after consulting a specialist on the necessity for the long-term use of Haemostop in your case.
- if you have had blood in your urine, it may lead to urinary tract obstruction.
- if you have a risk of having blood clots.
- if you have a previous history of blood clots (thrombus) that breaks loose and is carried by the blood stream to plug another vessel in the lung, brain, gastrointestinal tract, kidneys or leg (thromboembolic disease) you should not receive Haemostop unless simultaneous treatment with anti-clotting medicines (anticoagulants) can be given.
- if you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation), Haemostop may not be right for you, except if you have acute severe bleeding and blood test have shown the process that inhibits blood clotting called fibrinolysis is activated.
- if you have renal impairment the dosage of Haemostop should be reduced.

Other medicines and Haemostop

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- other medicines that help blood to clot called antifibrinolytic medicines
- medicines that prevent blood clotting, called thrombolytic medicines
- oral contraceptives

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving Haemostop. Haemostop is not recommended during pregnancy.

Haemostop is excreted in human milk. Therefore, the use of Haemostop during breastfeeding is not recommended.

Driving and using machines

No studies have been performed on the ability to drive and use machines.
Side effects of Haemostop include visual disturbances and dizziness. If you experience these side affects you are advised not to drive or handle machinery.

It is not always possible to predict to what extent Haemostop may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or using machines until you are aware of the measure to which Haemostop affects you.

3. How to use Haemostop

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself Haemostop. It will be given to you by a person who is qualified to do so.

Haemostop will be given to you by slow injection or infusion into a vein.

Use in children

Data on efficacy and safety in children are limited.

Use in elderly

No reduction in dosage is necessary unless there is evidence of renal failure.

Use in patients with kidney problem

If you have a kidney problem, your dose of tranexamic acid will be reduced according to a test performed on your blood (serum creatinine level).

Method of administration

Haemostop should only be administered slowly into a vein.

Haemostop must not be injected into a muscle.

Your doctor will tell you how long your treatment with Haemostop will last. If you have the impression that the effect of Haemostop is too strong or too weak, tell your doctor or pharmacist.

If you use more Haemostop than you should

Since a healthcare provider will administer Haemostop, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use Haemostop

Since a healthcare provider will administer Haemostop, it is unlikely that the dose will be missed.

4. Possible side effects

Haemostop can have side effects.

Not all side effects reported for Haemostop are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Haemostop, please consult your healthcare provider for advice.

If any of the following happens, stop receiving Haemostop and tell your doctor immediately and go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Haemostop. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- convulsions (fits)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- diarrhoea
- vomiting
- nausea

Less frequent side effects:

- red, itchy rash

Side effects with unknown frequency

- vision disturbances including impaired colour vision
- malaise with hypotension (low blood pressure), with or without loss of consciousness, especially if the injection is given too quickly
- blood clots

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Haemostop.

5. How to store Haemostop

Store all medicines out of reach of children.

Store at or below 25 °C and protect from light.

Do not freeze.

Do not use this medicine after the expiry date which is stated on the syringe or pen label and on the outer carton after EXP. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Haemostop contains

The active substance is tranexamic acid.

The other ingredient is water for injection.

What Haemostop looks like and contents of the pack

Haemostop is a clear, colourless solution.

Haemostop is supplied in Type I clear glass 5 mL ampoules in an outer carton, each ampoule containing 500 mg tranexamic acid. The ampoules are packed in pocket ampoules in unit boxes, five ampoules per box.

Not all pack sizes may be marketed.

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