PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

HEMOPRON® 500, 100 mg/mL solution for injection or infusion

HEMOPRON® 1 000, 100 mg/mL solution for injection or infusion

Tranexamic acid

Sugar free

Read all of this leaflet carefully before you are given

HEMOPRON

- 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 HEMOPRON is and what it is used for

The active ingredient, tranexamic acid, belongs to a group of medicines called coagulants (haemostatics).

HEMOPRON may be used for the short-term prevention and treatment of bleeding disorders e.g. in patients who are undergoing minor surgery, menorrhagia (menstrual periods with abnormally heavy or prolonged bleeding) and hereditary angioedema (a genetic disease that causes swelling of the skin and tissue just beneath the skin).

2. What you need to know before you use HEMOPRON

HEMOPRON should not be administered to you, if you:

- are hypersensitive (allergic) to tranexamic acid or any of the other ingredients of HEMOPRON;
- have bleeding in the brain membranes (the main symptom is a sudden, severe headache);
- have a condition called 'consumption coagulopathy' where blood in the whole body starts to clot;
- have a history of convulsions (fits);
- have urinary tract bleeding.

Warnings and precautions

Convulsions (fits) have been reported with HEMOPRON, particularly at high doses (see **HEMOPRON should not be administered to you** and section 4, **Possible Side Effects**).

Tell your doctor before being given HEMOPRON if you:

- have a condition (high blood pressure, high blood cholesterol) that may cause the formation of blood clots;
- have vision problems, as your colour vision may be affected with long-term treatment with HEMOPRON. If necessary, your doctor will consider

stopping the treatment. If you receive HEMOPRON for an extended period, you should have regular ophthalmologic eye examinations;

- have had blood in your urine, it may lead to urinary tract obstruction;
- had a stroke, or someone in your family had a stroke as you will have an increased risk of having blood clots;
- take hormonal contraceptives or hormone replacement therapy, as you will have an increased risk of having blood clots;
- have impaired kidney or liver function.
- Patients with very heavy irregular menstrual bleeding should not use [HEMOPRON] until the cause of the irregularity has been established;
- If you receive Factor IX Complex Concentrate (medicine made up of blood clotting factors) or Anti-inhibitor Coagulant Concentrate (medicine used to control bleeding related to surgery in people with haemophilia and inhibitors), you should not receive HEMOPRON concomitantly, as the risk of thrombosis may be increased.

Other medicines and HEMOPRON

Always tell your healthcare provider if you are taking any other medicine. This includes all complementary or traditional medicines.

This is especially important with the following medicines:

- other medicines that help blood to clot, called antifibrinolytic medicines;
- medicines that prevent blood clotting, called anticoagulant or thrombolytic medicines;
- oestrogens (as in oral contraceptives or hormone replacement therapy).

Pregnancy and breastfeeding

The safety of HEMOPRON has not been established in pregnancy.

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 HEMOPRON is administered to you.

HEMOPRON is excreted in human milk. Therefore, the use of HEMOPRON during breast-feeding is not recommended.

Driving and using machines

HEMOPRON may make you feel dizzy and affect your vision. Do not drive or use tools or machines as HEMOPRON could interfere with your ability to drive safely. Do not operate any tools or machines.

3. How to use HEMOPRON

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

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

HEMOPRON is only intended for slow administration into a vein; it may not be injected into a muscle or any other route.

Adults: The usual dose range in adults is 1 000 mg to 1 500 mg (10 – 15 mL) every 8 hours. This will usually be given by a slow injection into your vein.

Your doctor will decide what dose you need and for how long you should be treated with HEMOPRON.

Children: Adequate information is not available.

Patients with kidney problems: If you have problems with your kidneys, your doctor will decide what dose to give you, based on a blood test.

If you have the impression that the effect of HEMOPRON is too strong or too weak, tell your doctor or healthcare professional.

If you receive more HEMOPRON than you should

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

If a dose of HEMOPRON has been missed

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

4. Possible side effects

HEMOPRON can have side effects.

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

Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- A blood clot in an artery (arterial thrombosis). Tell your doctor if you have chest pain, shortness of breath and dizziness.
- A blood clot in a vein (venous thrombosis). Tell your doctor if you have swelling, redness and pain in your foot, ankle, or leg, usually on one side.

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

Tell your doctor or healthcare professional if any of the following side effects get serious or lasts longer than a few days:

- Affected eyesight, including impaired colour vision.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea (feeling sick)
- Vomiting (being sick)
- Diarrhoea (loose bowels).

Less frequent side effects:

- Skin rashes, itching.

Unknown frequency of side effects:

- Dizziness
- Convulsions (fits)
- Muscle pain
- Feeling unwell and having too low blood pressure (you may feel dizzy and faint if you get up; your doctor will test your blood pressure to confirm).

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 on the SAHPRA website: "6.04 Adverse Drug Reactions 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 HEMOPRON.

5. How to store HEMOPRON

Store all medicines out of reach of children.

Store the ampoules at or below 25 °C. Keep ampoules in carton to protect from light.

After first opening: The solution for injection is for single use only. Unused solution for injection should be discarded. Chemical and physical in-use stability of the infusion solutions have been demonstrated for 24 hours at 2 - 8 °C. Mixtures not used within 24 hours of preparation should be discarded. Do not freeze.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Do not use after the expiry date, indicated on the label.

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 HEMOPRON contains

The active substance is tranexamic acid.

Each 5 mL of the solution contains 500 mg of tranexamic acid.

Each 10 mL of the solution contains 1 000 mg of tranexamic acid.

The other ingredient is water for injections.

What HEMOPRON looks like and contents of the pack

HEMOPRON solution for injection/infusion is a clear, sterile solution free from visible particles, packed in type I transparent glass ampoules of 5 mL and of 10 mL, providing 100 mg tranexamic acid per mL.

Pack sizes: 5 x 5 mL or 5 x 10 mL ampoules, packed in an outer carton.

Not all pack sizes may be marketed.

Holder of the certificates of registration

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