GALENICA SENESE			
DIECUT	PRODUCT **FOLDING SCHEME 153X616/44**		
DIMENSION OPEN (mm) **153X616**	DIMENSION FOLDED (mm) **153X44**	CODE **153X616/44**	SCALE **1.1**
COLORS TECHNICAL COLORS **Cutline - Fold - Dimension and info - Code position**			
PAPER **USOMANO**	GRAMMAGE gr. m^2 **40**	**4 MM UNGHIATURA**	

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0	**09/09/2025**

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153 mm

40 mm

44 mm

616 mm

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

HEMOPRON® 500, solution for injection/infusion
HEMOPRON® 1 000, solution for injection/infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL ampoule contains 500 mg tranexamic acid (100 mg/mL solution for injection).
Each 10 mL ampoule contains 1 000 mg tranexamic acid (100 mg/mL solution for injection).
Sugar free
For the full list of excipients, see **section 6.1**.

3. PHARMACEUTICAL FORM

Solution for injection/ infusion.
A clear sterile solution, free from particles, with pH of 6,5 - 8,0.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications
- Short term use in the treatment of hyphaema and in patients with established coagulopathies who are undergoing minor surgery.
- Management of dental extraction in haemophiliacs.
- Hereditary angioedema.
- Menorrhagia.

4.2. Posology and method of administration
Posology
Adults
Administration by injection is normally changed to oral administration of an oral dosage form of tranexamic acid after a few days.
Traumatic hyphaema:
1,0 to 1,5 g every 8 hours for six to seven days.
Patients with established coagulopathies undergoing minor surgery:
Conisation of the cervix: 1,0 to 1,5 g every 8 to 12 hours postoperatively.
Dental operations/extractions in haemophiliacs:
Two hours before the operation, 25 mg/kg of **HEMOPRON** is given, as well as Factor VIII and Factor IX. After the operation, tranexamic acid at a dosage of 25 mg/kg is given 3 to 4 times a day for 6 to 8 days (normally as an oral dosage form).
Hereditary angioedema:
Some patients are aware of the onset of illness; a suitable treatment for these patients is 1,0 - 1,5 g two to three times daily for some days. Other patients are treated continually at this dosage.
Menorrhagia:
1,0 - 1,5 g three to four times daily (normally as an oral dosage form), given at the onset of heavy bleeding for the duration of the period.
Renal impairment
For patients with impaired renal function, **HEMOPRON** should be given with caution (see **section 4.4**). Dosages should be reduced in patients with renal impairment. For patients with moderate to severe impaired renal function, the following dosages are recommended:

Serum creatinine (micromole/L)	Intravenous dose
120 - 250	10 mg/kg body weight twice daily
250 - 500	10 mg/kg body weight daily
> 500	5 mg/kg body weight daily

Children
Data on efficacy and safety in children are limited.
Administration
HEMOPRON solution for injection is strictly limited to slow intravenous infusion (see **section 6.6**), or slow injection over a period of at least five minutes, i.e. 1 mL/minute. See sections 4.3 and 4.4.

4.3. Contraindications
- Hypersensitivity to tranexamic acid, or to any of the excipients of **HEMOPRON**.
- In cases of massive upper urinary tract haemorrhage, **HEMOPRON** should be avoided to reduce the risk of ureteric obstruction.
- Patients with a pronounced thrombotic tendency or colour vision disorder (see **section 4.4**).
- Thrombophlebitis, impaired liver function and subarachnoid bleeding.
- Fibrinolytic conditions following consumption coagulopathy except in those with predominant activation of the fibrinolytic system with acute severe bleeding (see **section 4.4**).
- History of convulsions.

4.4. Special warnings and precautions for use
The indications for use and method of administration should be followed strictly:
- Intravenous injections should be given very slowly.
- **HEMOPRON** must **not** be administered by the intramuscular route.
- Intrathecal and intraventricular injection, intracerebral application (risk of cerebral oedema and convulsions).

Convulsions
Convulsions have been reported in association with tranexamic acid, as in **HEMOPRON** treatment. In coronary artery bypass graft (CABG) surgery, most of these cases were reported following intravenous (IV) injection of tranexamic acid, as in **HEMOPRON**, in high doses.
Visual disturbances
The patient should be monitored for visual disturbances, including visual impairment, blurred vision, impaired colour vision. If necessary, **HEMOPRON** should be discontinued.
With continuous long-term use of **HEMOPRON**, regular ophthalmologic examinations (eye examinations including visual acuity, colour vision, fundus, visual field etc.) are indicated (see **section 4.3**). With pathological ophthalmic changes, particularly with diseases of the retina, it is recommended that the medical practitioner consult a specialist on the necessity for long-term use of **HEMOPRON** in each individual case.
Haematuria
In case of haematuria from the upper urinary tract, there is a risk for urethral obstruction (see **section 4.3**).
Thromboembolic events
Before use of **HEMOPRON**, risk factors of thromboembolic disease should be considered. In patients with a history of thromboembolic diseases or in those with increased incidence of thromboembolic events in their family history (patients with an elevated risk of thrombophilia), **HEMOPRON** should not be administered (see **section 4.3**).
HEMOPRON should be administered with care in patients receiving oral contraceptives because of the increased risk of thrombosis (see **section 4.5**).
Disseminated intravascular coagulation
Patients with disseminated intravascular coagulation (DIC) should not be treated with **HEMOPRON** (see **section 4.3**). If **HEMOPRON** is given it should be restricted to those in whom there is predominant activation of the fibrinolytic system with acute severe bleeding.
Patients with menorrhagia (irregular menstrual bleeding) should not use **HEMOPRON** until the cause of irregularity has been established.
Tranexamic acid should not be concomitantly administered with Factor IX Complex Concentrate or Anti-inhibitor Coagulant Concentrate, as the risk of thrombosis may be increased.
Characteristically, the haematological profile approximates to the following: reduced euglobulin clot lysis time; prolonged prothrombin time; reduced plasma levels of fibrinogen, factors V and VIII, plasminogen fibrinolysin and alpha-2 macroglobulin; normal plasma levels of P and P complex; i.e. factors II (prothrombin), VIII and X; increased plasma levels of fibrinogen degradation products; a normal platelet count.
The foregoing presumes that the underlying disease state does not of itself modify the various elements in this profile. In such acute cases, a single dose of 1 g **HEMOPRON** is frequently sufficient to control bleeding. Administration of **HEMOPRON** in DIC should be considered only when appropriate haematological laboratory facilities and expertise are available.
Patients with a previous history of thromboembolic disease should not be given HEMOPRON unless simultaneous treatment with anticoagulants can be given (see **section 4.3**).
Liver function
Liver function tests should be performed if **HEMOPRON** is used long-term (see **section 4.3**).
Renal impairment
For patients in renal failure, **HEMOPRON** should be given with caution because of the risk of accumulation. Dosage should be reduced in patients with renal impairment (see **section 4.2**).

4.5. Interaction with other medicines and other forms of interaction
Medicines with actions on haemostasis should be given with caution to patients on **HEMOPRON**.
Simultaneous treatment with anticoagulants should take place under the strict supervision of a doctor with experience in this field.
There is a risk of increased thrombus-formation potential, such as with oestrogens. Alternatively, the antifibrinolytic action of **HEMOPRON** may be antagonised with thrombolytic medicines.

4.6. Fertility, pregnancy and lactation
Women of childbearing potential
Women of childbearing potential have to use effective contraception during treatment.
Pregnancy
The safety of **HEMOPRON** has not been established in pregnancy.
Breastfeeding
Tranexamic acid passes into breast milk at a concentration of a hundredth of the corresponding serum levels. Therefore, breastfeeding is not recommended.
Fertility
There are no clinical data on the effects of tranexamic on fertility.

4.7. Effects on ability to drive and use machines
Side effects of **HEMOPRON** include visual disturbances and dizziness. Patients should be advised against driving and handling machinery if they develop these symptoms.

4.8. Undesirable effects

Tabulated list of adverse reactions

System organ class	Frequent	Less frequent	Frequency not known
Immune system disorders			Hypersensitivity reactions including anaphylaxis
Nervous system disorders			Dizziness, convulsions particularly in case of misuse (see **sections 4.3 and 4.4**)
Eye disorders		Retinal/arterial occlusion	Visual disturbances including impaired colour vision (see **section 4.4**)
Vascular disorders		Thromboembolic events	Malaise with hypotension, with or without loss of consciousness (generally following a too fast intravenous injection) Arterial or venous thrombosis at any sites
Gastrointestinal disorders	Diarrhoea Vomiting Nausea		
Skin and subcutaneous tissue disorders		Dermatitis allergic	
Musculoskeletal, connective tissue and bone disorders			Musculoskeletal pain

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions 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**

4.9. Overdose
Symptoms:
Dizziness, headache, nausea and vomiting, diarrhoea. Faintness and hypotension may occur.
Treatment would consist of enhancing diuresis (with fluids plus diuretics) and symptomatic treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Category A, class 8.1: Coagulants, haemostatics
Tranexamic acid exerts an inhibitory effect on the activation of plasminogen in the fibrinolytic system, i.e. on the conversion of plasminogen to plasmin. Tranexamic acid is used in fibrinolytic bleeding conditions, which may occur in a number of different clinical conditions in which there is abnormal stimulation of the activation mechanism.

5.2. Pharmacokinetic properties
Absorption
Peak plasma concentrations of tranexamic acid are obtained rapidly after a short intravenous infusion after which plasma concentrations decline in a multi-exponential manner.
Distribution
The plasma protein binding of tranexamic acid is about 3 % at therapeutic plasma levels and seems to be fully accounted for by its binding to plasminogen.
Tranexamic acid does not bind to serum albumin. The initial volume of distribution is about 9 to 12 litres.
Tranexamic acid crosses the placenta and may reach one hundredth of the serum peak concentration in the milk of lactating women.
Tranexamic acid crosses the blood brain barrier.
Elimination
Tranexamic acid is excreted in the urine mainly as the unchanged medicine.
Urinary excretion via glomerular filtration is the main route of elimination. Renal clearance is equal to plasma clearance (110 to 116 mL/min). Excretion of tranexamic acid is about 90 % within the first 24 hours after intravenous administration of 10 mg/kg body weight. Elimination half-life of tranexamic acid is approximately 3 hours.
Other special populations
Plasma concentrations increase in patients with renal failure.
No specific pharmacokinetic study has been conducted in children.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Water for injection

6.2. Incompatibilities
HEMOPRON should not be mixed with blood and infusion solutions containing penicillin.

6.3. Shelf life
30 months.
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.

6.4. Special precautions for storage
Store the ampoules at or below 25 °C. Keep ampoules in carton to protect from light.
For storage conditions after first opening of **HEMOPRON**, see **section 6.3**.

6.5. Nature and contents of container
Type I transparent glass ampoules packed in a cardboard carton.
Each carton contains 5 x 5 mL or 5 x 10 mL ampoules.
Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling
For intravenous infusion, **HEMOPRON** may be mixed with 0,9 % sodium chloride solution, 5 % glucose solution and Ringer's solution (compound sodium chloride).
The required volume may be added to the chosen infusion solution to achieve final concentrations of 1 gram or of 2 grams in 100 mL (1 % or 2 %).
The mixed solutions should be used immediately after preparation (see **section 6.3**).
HEMOPRON is for single use only. Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATES OF REGISTRATION
Macleods Pharmaceuticals SA (Pty) Ltd.
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext 12, Alberton.
Tel: +27 11 682 1169

8. REGISTRATION NUMBERS
HEMOPRON 500: 52/8.1/0808
HEMOPRON 1 000: 52/8.1/0809

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION
13.07.2021

10. DATE OF REVISION OF THE TEXT
09.09.2021

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
2. What you need to know before you use **HEMOPRON**
3. How to use **HEMOPRON**
4. Possible side effects
5. How to store **HEMOPRON**
6. Contents of the pack and other information

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.

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GALENICA SENESE			
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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 breastfeeding is not recommended.

Driving and using machines
HEMOPRON may make you feel dizzy and affect your vision. Do not drive 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
Macleods Pharmaceuticals SA (Pty) Ltd.
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext 12, Alberton.
Tel: +27 11 682 1169

This leaflet was last revised in
09.09.2021

Registration numbers
HEMOPRON 500: 52/8.1/0808
HEMOPRON 1 000: 52/8.1/0809

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

HEMOPRON® 500, 100 mg/mL oplossing vir inspuiting of infusie
HEMOPRON® 1 000, 100 mg/mL oplossing vir inspuiting of infusie
Traneksamiensuur
Suikervry

Lees die hele pamflet noukeurig deur voordat HEMOPRON aan jou gegee
- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy nog vrae het, raadpleeg asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie pamflet
1. Wat **HEMOPRON** is, en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy **HEMOPRON** gebruik
3. Hoe om **HEMOPRON** te gebruik
4. Moontlike newe-effekte
5. Hoe om **HEMOPRON** te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat HEMOPRON is en waarvoor dit gebruik word
Die aktiewe bestanddeel, traneksamiensuur, behoort tot 'n groep medisyne genaamd stolmiddels (hemostatika).
HEMOPRON kan gebruik word vir die korttermyn voorkoming en behandeling van bloedingsiektes, bv. by pasiënte wat 'n klein operasie ondergaan, met menorragie (maandstondes met abnormale swaar of langdurige bloeding) en oorerflike angio-edeem ('n genetiese siekte wat swelling in die vel en weefsel net onder die vel veroorsaak).

2. Wat jy moet weet voordat jy HEMOPRON gebruik
HEMOPRON moet nie aan jou toegedien word nie, as jy:
- hipersensitief (allergies) is vir traneksamiensuur of vir enige van die ander bestanddele van **HEMOPRON**;
- bloeding het in die breinvliese (die hoofsimptoom is 'n skielike, erge hoofpyn);
- 'n toestand het wat 'verbruikskoagulopatie' genoem word, waar bloed in die hele liggaam begin om te stol;
- jy 'n geskiedenis het van stuiptrekkings (stuipe);
- bloeding in die urienweg het.

Waarskuwings en voorsorgmaatreëls
Konvulsies (stuipe) is gerapporteer met **HEMOPRON**, veral by hoë dosisse (kyk **HEMOPRON moet nie aan jou toegedien word nie** en **afdeling 4, Moontlike newe-effekte**).

Voordat **HEMOPRON** aan jou toegedien word, sê vir jou dokter as jy:
- 'n siektetoestand het wat die vorming van bloedklonte kan veroorsaak (hoë bloeddruk, hoë bloed cholesterol);
- sigprobleme het, want jou kleurvisie kan met langtermyn behandeling met **HEMOPRON** aangetas word. Indien nodig, sal jou dokter oorweeg om die behandeling te staak. As jy **HEMOPRON** vir 'n lang tydperk ontvang, moet jy gereeld vir 'n oogondersoek gaan;
- bloed in jou urien gehad het; dit kan tot obstruksie van die urienweg lei;
- 'n beroerte gehad het, of iemand in jou familie 'n beroerte gehad het, aangesien jy 'n verhoogde risiko sal hê om bloedklonte te kry;
- hormonale voorbehoedmiddels neem, of hormoonvervangingsterapie, aangesien jy 'n verhoogde risiko het om bloedklonte te kry;
- belemmerde nier- of lewerfunksie het;
- Pasiënte met baie swaar onreëlmatige maandstondes moet nie **HEMOPRON** ontvang voordat die oorsaak van die afwyking vasgestel is nie.
- As jy Faktor IX-kompleks konsentraat ontvang ('n medisyne wat bestaan uit bloedstollingsfaktore) of 'n anti-inhibitor koagulantkonsentraat (medisyne wat gebruik word om bloeding te beheer wat verband hou met chirurgie by mense met hemofilie en inhibitore), moet jy nie gelyktydig **HEMOPRON** ontvang nie, aangesien die risiko van trombose verhoog kan word.

Ander medisynes en HEMOPRON
Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. Dit sluit alle komplementêre of tradisionele medisyne in.

Dit is veral belangrik vir die volgende medisyne:
- ander medisyne wat help om die bloed te laat stol, genaamd antifibrinolitiese medisyne;
- medisyne wat bloedstolling voorkom, genaamd antistolmiddels of trombolitiese medisynes;
- estrogene (soos in mondelike voorbehoedmiddels of hormoonvervangingsterapie).

Swangerskap en borsvoeding
Die veiligheid van **HEMOPRON** met swangerskap is nie vasgestel nie.
Indien jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat **HEMOPRON** aan jou toegedien word.
HEMOPRON word in mensmelk uitgeskei. Daarom word die gebruik van **HEMOPRON** tydens borsvoeding nie aanbeveel nie.

Bestuur en gebruik van masjinerie
HEMOPRON kan jou duiselig laat voel en jou sig aantas. Moenie bestuur nie want **HEMOPRON** kan jou vermoë om veilig te bestuur aantas. Moenie enige gereedskap of masjinerie hanteer nie.

3. Hoe om HEMOPRON te gebruik
Moenie medisyne wat vir jou voorgeskryf is met ander mense deel nie.
Daar sal nie van jou verwag word om **HEMOPRON** aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen.
HEMOPRON is slegs bedoel vir stadige toediening in 'n aar; dit mag nie in 'n spier of op enige ander manier ingespuit word nie.
Volwassenes: Die gewone dosisreeks vir volwassenes is 1 000 mg tot 1 500 mg (10 - 15 mL) elke 8 uur. Dit sal gewoonlik deur 'n stadige inspuiting in jou aar toegedien word.
Jou dokter sal besluit watter dosis jy moet ontvang en vir hoe lank jy met **HEMOPRON** behandel moet word.
Kinders: Voldoende inligting is nie beskikbaar nie.
Pasiënte met nierprobleme: As jy probleme met jou niere het sal jou dokter op grond van 'n bloedtoets besluit watter dosis om aan jou te gee.
Indien jy die indruk kry dat die effek van **HEMOPRON** te sterk of te swak is, lig jou dokter of gesondheidsorgkundige in.
Indien jy meer HEMOPRON ontvang as wat jy moes
Aangesien 'n gesondheidsorgverskaffer **HEMOPRON** sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering behandel.
Indien 'n dosis van HEMOPRON oorgeslaan is
Aangesien 'n gesondheidsorgverskaffer **HEMOPRON** sal toedien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

4. Moontlike newe-effekte
HEMOPRON kan newe-effekte hê.
Nie alle newe-effekte wat vir **HEMOPRON** aangemeld is word by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan, of jy enige ongunstige effekte ervaar terwyl jy **HEMOPRON** ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer.
Sê dadelik vir jou dokter as jy enige van die volgende ernstige newe-effekte opmerk - jy kan dringende mediese aandag benodig:
- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik maak om te sluk of asem te haal.
- 'n Bloedklont in 'n arterie (arteriële trombose). Sê vir jou dokter as jy pyn op die bors, kortasemrigheid en duiseligheid ervaar.
- 'n Bloedklont in 'n aar (veneuse trombose). Lig jou dokter in as jy swelling, rooiheid en pyn in jou voet, enkel of been het, gewoonlik aan die een kant.

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, kan jy moontlik 'n ernstige reaksie op **HEMOPRON** hê. Jy kan dringende mediese aandag of hospitalisering benodig.
Sê vir jou dokter of gesondheidsorgkundige indien enige van die volgende newe-effekte ernstig raak of langer as 'n paar dae duur:
- Aangetaste sig, insluitend verswakte kleurvisie.

Dit is 'n ernstige newe-effek. Jy kan dringende mediese aandag benodig.
Lig jou dokter in as jy enige van die volgende waarneem:
Gereelde newe-effekte:
- Naarheid (mislike gevoel)
- Braking (opbring)
- Diarree (maagwerkings).

Minder gereelde newe-effekte:
- Veluitslag, jeuk.

Onbekende frekwensie van newe-effekte:
- Duiseligheid
- Konvulsies (stuipe)
- Spierpyn
- Ongesteldheid en te lae bloeddruk (jy kan duiselig en flou voel as jy opstaan; jou dokter sal jou bloeddruk toets om dit te bevestig).

Indien jy enige newe-effekte waarneem wat nie in hierdie pamflet vermeld word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte ervaar, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer op die SAHPRA-webwerf: "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn onder SAHPRA se publikasies verskyn: **https://www.sahpra.org.za/Publications/Index/8**. Deur newe-effekte aan te meld, kan jy meer inligting verskaf oor die veiligheid van **HEMOPRON**.

5. Hoe om HEMOPRON te bewaar
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Bewaar die ampules by of benede 25 °C. Hou die ampules in die karton om die inhoud teen lig te beskerm.
Nadat dit oopgemaak is: Die oplossing vir inspuiting is slegs vir enkelgebruik. Alle ongebruikte oplossing vir inspuiting moet weggegooi word. Chemiese en fisiese stabiliteit tydens die gebruik van die infusie-oplossings is vir 24 uur lank by 2 - 8 °C getoon. Mengsels wat nie binne 24 uur na bereiding gebruik word nie, moet weggegooi word. Moenie vries nie.
Vanuit 'n mikrobiologiese oogpunt moet die produk dadelik gebruik word. Indien dit nie dadelik gebruik word nie, is die bergingstyd gedurende en bergingstoestande voor gebruik die gebruiker se verantwoordelikheid.
Moenie na die vervaldatum op die etiket gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting
Wat HEMOPRON bevat
Die aktiewe bestanddeel is traneksamiensuur.
Elke 5 mL van die oplossing bevat 500 mg traneksamiensuur.
Elke 10 mL van die oplossing bevat 1 000 mg traneksamiensuur.
Die ander bestanddeel is water vir inspuiting.

Hoe HEMOPRON lyk en wat die inhoud van die pakkie is
HEMOPRON oplossing vir inspuiting/infusie is 'n deursigtige, steriele oplossing vry van sigbare deeltjies, verpak in tipe I deursigtige glasampules van 5 mL en 10 mL, wat 100 mg traneksamiensuur per mL lewer.
Verpakkingsgroottes: 5 x 5 mL of 5 x 10 mL ampules, verpak in 'n kartonhouer.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die registrasiesertifikate
Macleods Pharmaceuticals SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos)
Cussoniarylaan 1, Bassonia Rock, Uitbr.12, Alberton.
Tel: +27 11 682 1169

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