KLOTIGO

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE
KLOTIGO 500 solution for injection/infusion
KLOTIGO 1 000 solution for injection/infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5 mL ampoule contains tranexamic acid 500 mg (100 mg/mL solution for injection).
Each 10 mL ampoule contains tranexamic acid 1 000 mg (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 haemorrhage or risk of haemorrhage in increased fibrinolysis or fibrinogenolysis. Local fibrinolysis occurs in the following conditions:
  - prostatectomy and bladder surgery
  - epistaxis
  - conisation of the cervix
  - traumatic hyphaema.
- 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.

Haemorrhage or risk of haemorrhage in increased fibrinolysis or fibrinogenolysis:
Standard treatment of local fibrinolysis
0,5 g (1 ampoule of 5 mL) - 1 g (2 ampoules of 5 mL) KLOTIGO by slow intravenous injection (IV) or infusion (= 1 mL/minute) two to three times daily.

Standard treatment of general fibrinolysis
1 g (2 ampoules of 5 mL) KLOTIGO by slow intravenous injection or infusion (= 1 mL/minute) every 6 - 8 hours, equivalent to 15 mg/kg body weight (BW).

Prostatectomy and bladder surgery
0,5 g (1 ampoule of 5 mL) - 1 g (2 ampoules of 5 mL) KLOTIGO by slow intravenous injection or infusion (1 mL/min), 2 - 3 times daily (the first injection being given during the operation)/for the first three days after surgery.

Epistaxis
1,0 g - 1,5 g every 8 - 12 hours for 10 days.

Conisation of the cervix
1,0 g - 1,5 g every 8 - 12 hours for 12 days post-operatively.

Traumatic hyphaemia
1,0 - 1,5 g every 8 hours for 6 - 7 days.

Dental operations/extractions in haemophiliacs:
Two hours before the operation, 25 mg/kg of KLOTIGO is given, as well as factor VIII and factor IX. After the operation, tranexamic acid at a dosage of 25 mg/kg is given three to four times a day for 6 - 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.

Special populations
Renal impairment
For patients with impaired renal function, KLOTIGO 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

Paediatric population
Data on efficacy and safety in children are limited.

Method of administration
KLOTIGO 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).
For intravenous injection, use immediately after opening. Diluted infusion solutions are stable in the refrigerator at 2 - 8 °C for up to 24 hours (see section 6.3).

4.3 Contraindications
KLOTIGO is contraindicated in:
- hypersensitivity to tranexamic acid or to any of the ingredients of KLOTIGO (see section 6.1)
- in cases of massive upper urinary tract haemorrhage, KLOTIGO should be avoided to reduce the risk of ureteric obstruction
- patients with 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
- history of acute venous or arterial thrombosis (see section 4.4)
- severe renal impairment (risk of accumulation)
- active intravascular clotting
- intrathecal and intraventricular injection, intracerebral application (risk of cerebral oedema and 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 (maximum 1 mL per minute)
- KLOTIGO must **not** be administered by the intramuscular route
- KLOTIGO must **not** be administered by intrathecal or intraventricular injection, or intracerebral application due to a risk of cerebral oedema and convulsions.

Convulsions
Convulsions have been reported in association with tranexamic acid, as in KLOTIGO, treatment. In coronary artery bypass graft (CABG) surgery, most of these cases were reported following intravenous (IV) injection of tranexamic acid, as in KLOTIGO, in high doses.
With the use of the recommended lower doses of KLOTIGO, the incidence of post-operative seizures was the same as that in untreated patients.

Visual disturbances
The patient should be monitored for visual disturbances, including visual impairment, blurred vision, impaired colour vision. If necessary, KLOTIGO should be discontinued.
With continuous long-term use of KLOTIGO, 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 KLOTIGO 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 KLOTIGO, 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), KLOTIGO is contraindicated (see section 4.3).
KLOTIGO 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 KLOTIGO (see section 4.3). If KLOTIGO 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 KLOTIGO until the cause of the irregularity has been established.
Tranexamic acid should not be administered concomitantly with factor IX complex concentrates or anti-inhibitor coagulant concentrates, 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 KLOTIGO is frequently sufficient to control bleeding. Administration of KLOTIGO 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 KLOTIGO unless simultaneous treatment with anticoagulants can be given (see section 4.3).

Liver function
Liver function tests should be performed if KLOTIGO is used long-term (see section 4.3).

Renal impairment
For patients in renal failure, KLOTIGO 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
No studies of interactions between KLOTIGO and other medicines have been conducted.
Medicines with actions on haemostasis should be given with caution to patients on KLOTIGO.
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 KLOTIGO may be antagonised with thrombolytic medicines.

4.6 Fertility, pregnancy and lactation
Women of childbearing potential
Women of childbearing potential must use effective contraception during treatment.

Pregnancy
The safety of KLOTIGO has not been established in pregnancy.

Breastfeeding
Tranexamic acid passes into breast milk at a concentration of one 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
No studies have been performed on the ability to drive and use machines.
Side effects of KLOTIGO 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	Frequency	Side Effects
Immune system disorders	*Frequency unknown*	Hypersensitivity reactions including anaphylaxis
Nervous system disorders	*Frequency unknown*	Dizziness (giddiness), convulsions, particularly in case of misuse (see sections 4.3 and 4.4)
Eye disorders	*Less frequent*	Visual disturbances including impaired colour vision (see section 4.4)
Cardiac disorders	*Less frequent*	Thromboembolic events
Vascular disorders	*Less frequent*	Malaise with hypotension, with or without loss of consciousness (generally following a too fast intravenous injection), arterial or venous thrombosis at any sites, thrombotic complications due to inappropriate use
Gastrointestinal disorders	*Frequent*	Diarrhoea, vomiting, nausea
Skin and subcutaneous tissue disorders	*Less frequent*	Dermatitis allergic
Musculoskeletal, connective tissue and bone disorders	*Frequency unknown*	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 professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose
Signs and symptoms:
Dizziness, headache, nausea, vomiting, diarrhoea and convulsions. It has been shown that convulsions tend to occur at higher frequency with increasing dose. Faintness and hypotension may occur.

Management of overdose:
Treatment would consist of enhancing diuresis (with fluids plus diuretics), activated charcoal therapy and symptomatic treatment.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antihaemorrhagics, antifibrinolytics, amino acids
ATC code: B02AA02
Pharmacological classification: A 8.1 Coagulants, haemostatics

Mechanism of action
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.
Tranexamic acid exerts an antihaemorrhagic activity by inhibiting the fibrinolytic properties of plasmin.
A complex involving tranexamic acid, plasminogen is constituted; the tranexamic acid being linked to plasminogen when transformed into plasmin.
The activity of the tranexamic acid-plasmin complex on the activity on fibrin is lower than the activity of free plasmin alone.
In vitro studies showed that high tranexamic dosages decreased the activity of complement.

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.
Tranexamic acid is absorbed and is excreted unchanged through the kidneys.

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 - 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.
Tranexamic acid diffuses rapidly into joint fluid and the synovial membrane. Following administration of an intravenous injection of 10 mg/kg to patients undergoing knee surgery, concentrations in the joint fluids were similar to those seen in corresponding serum samples. The concentration of tranexamic acid in a number of other tissues is a fraction of that observed in the blood (breast milk, one hundredth; cerebrospinal fluid, one tenth; aqueous humour, one tenth). Tranexamic acid has been detected in semen where it inhibits fibrinolytic activity but does not influence sperm migration.

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 - 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.

Pharmacokinetics in special patient groups
Plasma concentrations increase in patients with renal failure.

Paediatric population
No specific pharmacokinetic study has been conducted in children.

5.3 Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Water for injection
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)

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

6.3 Shelf life
3 years.
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. 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 freeze.

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 KLOTIGO, see section 6.3.

6.5 Nature and contents of container
Type 1 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, KLOTIGO 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 g or of 2 g in 100 mL (1 % or 2 %).
The mixed solutions should be used immediately after preparation (see section 6.3).
KLOTIGO is for single use only. Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
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8. REGISTRATION NUMBERS
KLOTIGO 500: A52/8.1/0806
KLOTIGO 1 000: A52/8.1/0807

9. DATE OF FIRST AUTHORISATION
27 July 2021

10. DATE OF REVISION OF THE TEXT
29 January 2025

Marketed by:
AFT Pharmaceuticals SA (Pty) Ltd

pharma dynamics

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

KLOTIGO 500 solution for injection or infusion
KLOTIGO 1 000 solution for injection or infusion
Tranexamic acid
Sugar free

Read all of this leaflet carefully before you are given KLOTIGO
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What KLOTIGO is and what it is used for
The active ingredient, tranexamic acid, belongs to a group of medicines called coagulants (haemostatics).

KLOTIGO may be used for the short-term prevention and treatment of bleeding disorders due to a process that inhibits blood clotting called fibrinolysis. You may have been prescribed it for one of the following:
- prostate or bladder surgery
- nose bleeds (epistaxis)
- abnormalities of the cervix
- bleeding inside the eye (hyphaema)
- tooth removal (dental extraction) in haemophiliacs
- hereditary angioedema (a genetic disease that causes swelling of the skin and tissue just beneath the skin)
- menorrhagia (menstrual periods with abnormally heavy or prolonged bleeding).

2. What you need to know before you are administered KLOTIGO
KLOTIGO should not be administered to you:
- if you are hypersensitive (allergic) to tranexamic or any of the other ingredients of KLOTIGO (see section 6)
- if you have had blood in your urine (urinary tract bleeding), it may lead to urinary tract obstruction
- if you are prone to develop blood clots, have blood clots (a condition called thrombophlepitis) or your colour vision is disturbed
- if you have impaired liver function
- if you have bleeding in the brain membranes (the main symptom is a sudden, severe headache)
- if you have a condition called 'consumption coagulopathy' (also called disseminated intravascular coagulation) where blood in the whole body starts to clot, blocking small blood vessels. Symptoms may include chest pain, shortness of breath, leg pain, problems speaking, or problems moving parts of the body
- if you have a history of convulsions (fits)
- if you currently have a disease leading to blood clots.

Warnings and precautions
Convulsions (fits) have been reported with KLOTIGO, particularly at high doses (see KLOTIGO should not be administered to you and section 4, Possible side effects).

Tell your doctor or healthcare professional before being given the injection:
- if you have vision problems, as your colour vision may be affected with long-term treatment with KLOTIGO. If necessary, your doctor will consider stopping the treatment. If you receive KLOTIGO for an extended period, you should have regular eye examinations
- if you had a stroke, or someone in your family had a stroke as you will have an increased risk of having blood clots or have a condition (high blood pressure, high blood cholesterol) that may cause the formation of blood clots
- if you take hormonal contraceptives or hormone replacement therapy, as you will have an increased risk of having blood clots
- if you have impaired kidney or liver function
- if you have had blood in your urine, it may lead to urinary tract obstruction, that can cause kidney damage, kidney stones and infection
- if you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation)
- if you have a risk of having blood clots and/or if you are receiving factor IX complex concentrates or anti-inhibitor coagulant concentrates as KLOTIGO may increase your risk of blood clotting.

Patients with very heavy irregular menstrual bleeding should not use KLOTIGO until the cause of the irregularity has been established.

Other medicines and KLOTIGO
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

This is especially important with the following medicines:
- other medicines that help blood to clot, called antifibrinolytic medicines or called factor IX concentrates or anti-inhibitor coagulant concentrates
- medicines that prevent blood clotting, called anticoagulant thrombolytic medicines
- oestrogens (as in oral contraceptives or hormone replacement therapy).

Pregnancy and breastfeeding
The safety of KLOTIGO has not been established in pregnancy.
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before KLOTIGO is administered to you.
KLOTIGO is excreted in human milk. Therefore, the use of KLOTIGO during breastfeeding is not recommended.

Driving and using machines
KLOTIGO may make you feel dizzy and affect your vision. Do not drive or use tools or machines as KLOTIGO could interfere with your ability to drive safely.
It is not always possible to predict to what extent KLOTIGO may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which KLOTIGO affects them.

3. How to use KLOTIGO
Do not share medicines prescribed for you with any other person.
You will not be expected to give yourself KLOTIGO. It will be given to you by a person who is qualified to do so.
KLOTIGO 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 1000 - 1500 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 KLOTIGO.

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 KLOTIGO is too strong or too weak, tell your doctor or pharmacist.

If you are administered more KLOTIGO than you should
Since a healthcare provider will administer KLOTIGO, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If they forget to administer a dose of KLOTIGO to you
Since a healthcare professional will administer KLOTIGO, it is unlikely that the dose will be missed.

4. Possible side effects
KLOTIGO can have side effects.
Not all side effects reported for KLOTIGO are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using KLOTIGO, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using KLOTIGO and tell your doctor immediately or 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 allergic reaction to KLOTIGO. 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:
- 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
- affected eyesight, including impaired colour vision.

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:
- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea (loose bowels).

Less frequent side effects:
- skin rashes, itching
- 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).

The following side effects have been reported but the frequency for them to occur is not known:
- dizziness (a sensation of whirling and a tendency to fall or stagger)
- convulsions (fits)
- 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of KLOTIGO. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store KLOTIGO
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 stated on the carton.
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 KLOTIGO contains:
The active substance is tranexamic acid.
Each 5 mL of the solution contains tranexamic acid 500 mg.
Each 10 mL of the solution contains tranexamic acid 1 000 mg.

The other ingredients are water for injections, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment).

What KLOTIGO looks like and contents of the pack
KLOTIGO 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.*

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Registration numbers
KLOTIGO 500: A52/8.1/0806
KLOTIGO 1 000: A52/8.1/0807

Marketed by:
AFT Pharmaceuticals SA (Pty) Ltd

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

KLOTIGO 500 oplossing vir inspuiting of infusie
KLOTIGO 1 000 oplossing vir inspuiting of infusie
Traneksaamsuur
Suikervry

Lees hierdie hele inligtingsblad deeglik deur, voordat KLOTIGO aan u toegedien word
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgverskaffer.

Inhoud van hierdie inligtingsblad

1. Wat KLOTIGO is en waarvoor dit gebruik word
Die aktiewe bestanddeel traneksaamsuur, behoort aan 'n groep medisyne wat stolmiddels genoem word (hemostatika).

KLOTIGO mag gebruik word vir korttermyn voorkoming en behandeling van bloedingsversteurings, deur 'n proses wat bloedstolling beperk en fibrinolise genoem word. Dit kon vir u voorgeskryf word vir een van die volgende:
- prostaat-, of blaasoperasie
- neusbloeding (epistakse)
- abnormaliteite van die serviks
- bloeding in die oog (hifeem)
- tandverwydering (tand ekstraksie) by hemofilie lyers
- oorerflike angio-edeem ('n genetiese siekte wat swelling van die vel en weefsel net onder die vel, veroorsaak)
- menorragie (menstruasie wat abnormaal erg is, of langdurige bloeding).

2. Wat u nodig het om te weet, voordat KLOTIGO aan u toegedien word
KLOTIGO moet nie aan u toegedien word:
- indien u hipersensitief (allergies) is vir traneksaamsuur, of vir enige van die ander bestanddele van KLOTIGO nie (sien afdeling 6)
- indien u bloed in u urine het nie (urienweg bloeding), aangesien dit mag lei to urienwegobstruksie
- indien u geneig is om bloedklonte te vorm, bloedklonte het ('n toestand genaamd tromboflebitis), of u kleurvisie versteur is nie
- indien u belemmerde lewerfunksie het nie
- indien u bloeding in die membrane van die brein het nie (die hoofsimptoom is 'n skielike, erge hoofpyn)
- indien u aan 'n toestand wat "verbruikskoagulopatie" genoem word, ly nie (ook verspreide intravaskulêre stolling genoem), waar bloed in die hele liggaam begin stol en 'n obstruksie in klein bloedvate veroorsaak. Simptome mag borspyn, asemnood, pyn in die bene, spraakprobleme of probleme om liggaamsdele te beweeg, insluit
- indien u 'n geskiedenis van konvulsies (stuipe), het nie
- indien u tans aan 'n siekte ly, wat bloedklonte kan veroorsaak nie.

Waarskuwings en voorsorgmaatreëls
Konvulsies (stuipe), is aangemeld met KLOTIGO, veral teen hoë doserings (sien KLOTIGO moet nie aan u toegedien word en afdeling 4, Moontlike newe-effekte).

Vertel u dokter, of gesondheidsorgdeskundige, voordat die inspuiting aan u toegedien word:
- indien u sigprobleme het, aangesien u kleurvisie aangetas mag word met langtermyn KLOTIGO behandeling. U dokter sal, indien nodig, oorweeg om u behandeling te staak. Indien u KLOTIGO oor 'n lang tydperk ontvang, moet u gereelde oogondersoeke, ondergaan
- indien u, of iemand in u familie, 'n beroerte gehad het, aangesien u 'n hoër risiko vir die vorming van bloedklonte mag toon, of 'n toestand het (hoë bloeddruk, hoë bloed cholesterol), wat die vorming van bloedklonte mag veroorsaak
- indien u hormonale voorbehoedmiddels neem, of hormoonvervangingsterapie gebruik, aangesien u 'n hoër risiko vir die vorming van bloedklonte mag toon
- indien u belemmerde nier-, of lewerfunksie het
- indien u bloed in u urine het, mag dit lei tot urienwegobstruksie, wat nierskade, nierstene en infeksie, mag veroorsaak
- indien u uitermatige stolling of bloeding regdeur u liggaam ondervind (verspreide intravaskulêre stolling)
- indien u 'n risiko vir bloedklonte het en/of faktor IX kompleks konsentrate, of anti-inhibitor koagulant konsentrate ontvang, aangesien KLOTIGO u risiko vir bloedstolling, mag verhoog.

Pasiënte met baie erge, ongereelde menstruele bloeding, moet nie KLOTIGO toegedien word, totdat die oorsaak van die onreëlmatigheid vasgestel is nie.

Ander medisyne en KLOTIGO
Vertel altyd u gesondheidsorgverskaffer, indien u enige ander medisyne neem. (Hierdie sluit aanvullende, of tradisionele medisyne in).

Dit is veral belangrik, met die volgende medisyne:
- ander medikasie wat bloedstolling bevorder, ook antifibrinolitiese medisyne of faktor IX konsentrate of anti-inhibitor koagulant konsentrate, genoem
- medisyne wat bloedstolling voorkom, en teenstol trombolitiese medisyne genoem word
- estrogene (soos 'n orale voorbehoedmiddel, of hormoonvervangingsterapie).

Swangerskap en borsvoeding
Die veiligheid van KLOTIGO is nie vasgestel tydens swangerskap nie.
Indien u swanger is, of u baba borsvoed, vermoed dat u swanger mag wees, of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat KLOTIGO aan u toegedien word.
KLOTIGO word in mensmelk uitgeskei. Die toediening van KLOTIGO tydens borsvoeding, word dus nie aanbeveel nie.

Bestuur en die hantering van masjiene
KLOTIGO mag u duiseling laat voel en u sig beïnvloed. Moet nie bestuur, of gereedskap of masjinerie hanteer nie, aangesien KLOTIGO met u vermoë om veilig te bestuur, mag inmeng.
Dit is nie altyd moontlik om te voorspel tot watter mate KLOTIGO met die daaglikse aktiwiteite van 'n pasiënt mag inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is tot watter mate KLOTIGO hulle aantas nie.

3. Hoe om KLOTIGO te gebruik
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Daar sal nie van u verwag word, om KLOTIGO aan uself toe te dien nie. Dit sal aan u toegedien word deur 'n gekwalifiseerde persoon.
KLOTIGO word slegs aangedui vir stadige toediening, in 'n aar; dit mag nie in 'n spier ingespuit word, of deur enige ander roete toegedien word nie.

Volwassenes:
Die gewone dosisreikwydte by volwassenes is 1 000 - 1 500 mg (10 - 15 mL), elke 8 uur. Dit sal gewoonlik deur middel van 'n stadige inspuiting, in u aar, toegedien word. U dokter sal u dosis bepaal en besluit vir hoe lank u behandeling met KLOTIGO sal duur.

Kinders:
Voldoende inligting is nie beskikbaar nie.

Pasiënte met nierprobleme:
Indien u nierprobleme het, sal u dokter, gegrond op 'n bloedtoets, u gepaste dosis bepaal.

Indien u onder die indruk is dat die uitwerking van KLOTIGO té sterk, of té swak is, vertel u dokter, of apteker.

Indien u meer KLOTIGO ontvang as wat u behoort
Aangesien 'n gesondheidsorgverskaffer KLOTIGO aan u sal toedien, sal hy/sy die dosis beheer. In die geval van 'n oordosering, sal u dokter egter die oordosering hanteer.

Indien hulle vergeet om 'n KLOTIGO dosis aan u toe te dien
Aangesien 'n gesondheidsorgdeskundige KLOTIGO aan u sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

4. Moontlike newe-effekte
KLOTIGO kan newe-effekte hê.
Nie alle newe-effekte wat vir KLOTIGO aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongunstige effekte ervaar, terwyl u KLOTIGO ontvang, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van KLOTIGO en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk en asemhaling mag bemoeilik
- uitslag of gejeuk
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ondervind, kon u 'n ernstige reaksie teenoor KLOTIGO ervaar het. U mag dringende mediese aandag, of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- 'n bloedklont in 'n arterie (arteriële trombose). Vertel u dokter indien u borspyn het, kortasem, of duiselig is
- 'n bloedklont in 'n aar (veneuse trombose) het. Vertel u dokter indien u swelling, rooiheid en pyn in u voet, enkel, of been ervaar; gewoonlik slegs aan een kant
- u sig is aangetas, insluitend belemmerde kleurvisie.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Algemene newe-effekte:
- naarheid (voel naar)
- braking (gooi op)
- diarree (los stoelgang).

Minder algemene newe-effekte:
- veluitslae, gejeuk
- voel ongesteld en ondervind bloeddruk wat te laag is (u mag duiselig en lighoofdig voel, wanneer u opstaan; u dokter sal u bloeddruk neem om dit te bevestig).

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms, is onbekend:
- duiseligheid ('n tolsensasie en 'n geneigdheid om te val of te steier)
- konvulsies (stuipe)
- bloedklonte.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter, of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aan SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word, aanmeld.
U kan help om meer inligting aangaande die veiligheid van KLOTIGO in te win, deur newe-effekte aan te meld. U kan ook 'n e-pos direk aan die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za, om die veiligheid van die produk te verseker.

5. Hoe om KLOTIGO te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar die ampules teen of benede 25 °C. Hou die ampules in die kartonhouer, om teen lig te beskerm.
Nadat dit vir die eerste keer oopgemaak word: Die oplossing vir inspuiting is slegs vir eenmalige gebruik. Ongebruikte oplossing vir inspuiting, moet weggegooi word. Chemiese en fisiese in-gebruik stabiliteit van die infusie oplossings, is bevestig vir 24 uur teen 2 - 8 °C. Oplossings wat nie binne 24 uur na voorbereiding gebruik word nie, moet weggegooi word. Moet nie vries nie.
Vanuit 'n mikrobiologiese oogpunt, moet die produk onmiddellik gebruik word. Indien dit nie onmiddellik gebruik word nie, word die verantwoordelikheid van in-gebruik bewaringstye en toestande voor gebruik, die van die gebruiker.
Moet nie na die vervaldatum, soos aangedui op die kartonhouer, gebruik nie.
Neem alle ongebruikte medisyne na u apteker terug. Moet nie ongebruikte medisyne in afvoerpype, of rioolstelsels (bv. toilette) weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat KLOTIGO bevat:
Die aktiewe bestanddeel is traneksaamsuur.
Elke 5 mL oplossing bevat traneksaamsuur 500 mg.
Elke 10 mL oplossing bevat traneksaamsuur 1 000 mg.

Die ander bestanddele is natriumhidroksied (vir pH aanpassing), soutsuur (vir pH aanpassing), water vir inspuitings.

Hoe KLOTIGO lyk en die verpakkingsinhoud
KLOTIGO 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 traneksaamsuur per mL voorsien.
Verpakkingshoeveelhede: 5 x 5 mL, of 5 x 10 mL ampules, verpak in 'n buitenste kartonhouer.
**Nie alle verpakkingsgroottes word noodwendig bemark nie.*

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Die inligtingsblad was voorheen hersien
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Registrasienommers
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Bemark deur:
AFT Pharmaceuticals SA (Edms.) Bpk.

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