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 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 hyphaemia 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 hyphaemia
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 post-operatively.

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 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, 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

Children
Data on efficacy and safety in children are limited.

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.

4.3 Contraindications
- hypersensitivity to tranexamic acid, or to any of the excipients of KLOTIGO
- 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.

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
- 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.

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 should not be administered (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
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 have to 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 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 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	*Unknown frequency*	Hypersensitivity reactions including anaphylaxis
Nervous system disorders	*Unknown frequency*	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)
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	*Unknown frequency*	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 via the "**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
Pharmacotherapeutic group: Antihaemorrhagics, Antifibrinolytics, Amino acids
ATC code: B02AA02
Pharmacological classification A 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
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. 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 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 gram or of 2 grams 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 CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House
Steenberg Office Park
Silverwood Close
Westlake, Cape Town
South Africa
7945

8. REGISTRATION NUMBERS
KLOTIGO 500: A52/8.1/0806
KLOTIGO 1 000: A52/8.1/0807*
* not marketed

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION
Date of registration: July 2021

B5677

pharma dynamics

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

KLOTIGO 500 100 mg/mL solution for injection or infusion
KLOTIGO 1 000 100 mg/mL 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, 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 e.g. of 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 KLOTIGO
KLOTIGO should not be administered to you, if you
- are hypersensitive (allergic) to tranexamic acid or any of the other ingredients of KLOTIGO
- 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 thrombophlebitis) or your colour vision is disturbed
- have impaired liver function
- have bleeding in the brain membranes (the main symptom is a sudden, severe headache)
- 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
- have a history of convulsions (fits).

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, before being given KLOTIGO, 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
- 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
- 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 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 all 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, 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 as KLOTIGO could interfere with your ability to drive safely. Do not operate any tools or machines.

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 1 000-1 500 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 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 healthcare professional.

If you receive 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 receiving KLOTIGO, 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 KLOTIGO. 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
- 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).

Side effects with unknown frequency:
- 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. 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 KLOTIGO.

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, 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 KLOTIGO 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 ingredients are water for injection, 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.

Holder of the Certificate of Registration
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House
Steenberg Office Park
Silverwood Close
Westlake, Cape Town
South Africa
7945
(+27) 21 707-7000

This leaflet was last revised in
July 2021

Registration numbers
KLOTIGO 500: A52/8.1/0806
KLOTIGO 1 000: A52/8.1/0807*
* not marketed

B5677

pharma dynamics

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

KLOTIGO 500 100 mg/mL oplossing vir inspuiting of infusie
KLOTIGO 1 000 100 mg/mL 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, verpleegster, of ander gesondheidsorgverskaffer.

Wat hierdie inligtingsblad bevat

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, bv. by pasiënte wie geringe operasies ondergaan, menorragie (menstruele siklusse, met abnormaal swaar, of langdurige bloeding) en oorerflike angio-edeem ('n genetiese siekte, wat swelling van die vel en weefsel onder die vel veroorsaak).

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
- bloed in u urine het nie (urienweg bloeding), aangesien dit mag lei to urienwegobstruksie
- vatbaar is om bloedklonte te vorm, bloedklonte het ('n toestand genaamd tromboflebitis), of u kleurvisie versteur is nie
- lewerkwale het nie
- bloeding in die membrane van die brein het nie (die hoofsimptoom is 'n skielike, erge hoofpyn)
- ly aan 'n toestand wat "verbruikskoagulopatie" genoem word nie (ook genaamd verspreide intravaskulêre stolling), waar bloed in die hele liggaam begin stol en klein bloedvate kan verstop. Simptome mag borspyn, kortasemheid, pyn in die bene, spraakprobleme of probleme om liggaamsdele te beweeg, insluit
- 'n geskiedenis van konvulsies (stuipe), het nie.

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

Vertel u dokter, voordat KLOTIGO 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 oftalmologiese (oogheelkundige) ondersoeke, ondergaan
- of u of iemand in u familie, 'n beroerte gehad het, aangesien u 'n hoër vatbaarheid vir die vorming van bloedklonte mag toon, of 'n toestand het (hoë bloeddruk, hoë bloed cholesterol) wat die vorming van bloedklonte mag veroorsaak
- hormonale voorbehoedmiddels neem, of hormoonvervangingsterapie gebruik, aangesien u 'n hoër vatbaarheid vir die vorming van bloedklonte mag toon
- belemmerde nier-, of lewerfunksie het.

Pasiënte met baie swaar, 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, genaamd anti-fibrinolitiese medisyne of faktor IX konsentrate of anti-inhibitor koagulant konsentrate
- ander medikasie wat bloedstolling voorkom, genaamd trombolitiese medikasie
- estrogene (as 'n orale voorbehoedmiddel, of hormoonvervangingsterapie).

Swangerskap en borsvoeding
Die veiligheid van KLOTIGO is nie vasgestel tydens swangerskap nie.
Indien u swanger is, of 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 menslike melk afgeskei. Dus, die toediening van KLOTIGO tydens borsvoeding, word nie aanbeveel nie.

Bestuur en die hantering van masjinerie
KLOTIGO mag u duiselig laat voel en u sig beïnvloed. Moet nie bestuur nie, aangesien KLOTIGO met u vermoë om veilig te bestuur, mag inmeng. Moet nie enige gereedskap, of masjinerie hanteer 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 ure. 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 gesondheidsorgdeskundige.

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

Indien 'n dosis KLOTIGO oorgeslaan is
Aangesien 'n gesondheidsorgverskaffer 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 verslg, of indien u enige ongewenste effekte ervaar, terwyl u KLOTIGO ontvang, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Vertel u dokter onmiddellik, indien u enige van die volgende ernstige newe-effekte opmerk – u mag dringende mediese behandeling benodig
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk en asemhaling mag bemoeilik
- 'n bloedklont in 'n arterie (ateriële trombose) het. 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 of pyn in u voet, enkel, of been ervaar; gewoonlik slegs aan een kant.

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

Vertel u dokter of gesondheidsorgdeskundige, indien enige van die volgende newe-effekte ernstig raak, of langer as 'n paar dae duur
- Sig is beïnvloed, insluitend belemmerde kleurvisie.

Hierdie is 'n ernstige newe-effek. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk
Newe-effekte wat dikwels voorkom:
- naarheid (voel ongesteld)
- braking (gooi op)
- diarree (los stoelgang).

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

Newe-effekte met onbekende frekwensie:
- duiseligheid ('n sensasie van rondtol en 'n geneigdheid om te val of te waggel)
- konvulsies (stuipe)
- bloedklonte.

Indien u enige newe-effekte ervaar, 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. U kan ook newe-effekte aan SAHPRA rapporteer via die "**6.04 Adverse Drug Reaction Reporting Form**" wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, help u om meer inligting aangaande die veiligheid van KLOTIGO in te win.

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 alleenlik vir enkelgebruik. 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 etiket, gebruik nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in dreine, of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting
Wat KLOTIGO bevat
Die aktiewe bestanddeel is traneksaamsuur.
Elke 5 ml oplossing bevat 500 mg traneksaamsuur.
Elke 10 ml oplossing bevat 1 000 mg traneksaamsuur.
Die ander bestanddele is natriumhidroksied (vir pH aanpassing), soutsuur (vir pH aanpassing), water vir inspuiting.

Hoe KLOTIGO lyk en die inhoud van die verpakking
KLOTIGO oplossing vir inspuiting/infusie, is 'n helder, 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.
Verpakkingsgroottes: 5 x 5 mL, of 5 x 10 mL ampules, verpak in 'n buitenste kartonhouer.
Nie alle verpakkingsgroottes word bemark nie.

Houer van die Registrasiesertifikaat
Pharma Dynamics (Edms) Bpk.
1ste Vloer Grapevine House
Steenberg Office Park
Silverwood Close
Westlake, Kaapstad
Suid-Afrika
7945
(+27) 21 707 – 7000

Die inligtingsblad was voorheen hersien
Julie 2021

Registrasienommers
KLOTIGO 500: A52/8.1/0806
KLOTIGO 1 000: A52/8.1/0807*
* nie bemark nie

B5677

pharma dynamics