PATIENT INFORMATION LEAFLET

KLOTIGO 500 SOLUTION FOR INJECTION OR INFUSION

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.

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* not marketed