

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****CYKLOCLOT 100 mg/ml solution for injection/infusion****Tranexamic acid****Sugar free****Read all of this leaflet carefully before you are given CYKLOCLOT**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What CYKLOCLOT is and what it is used for
2. What you need to know before you are given CYKLOCLOT
3. How to use CYKLOCLOT
4. Possible side effects
5. How to store CYKLOCLOT
6. Contents of the pack and other information

1. What CYKLOCLOT is and what it is used for

CYKLOCLOT contains tranexamic acid which belongs to the class of medicines—called antifibrinolytics. CYKLOCLOT is used to prevent or reduce bleeding in certain conditions, minor surgery such as dental surgery in people with hereditary blood clotting disorders and bleeding inside the eye.



2. What you need to know before you are given CYKLOCLOT

CYKLOCLOT should not be administered to you:

- If you are hypersensitive (allergic) to tranexamic acid or any of the other ingredients of CYKLOCLOT (listed in section 6).
- If you have currently a disease leading to blood clots
- If you have a condition called 'consumption coagulopathy' where blood in the whole body starts to clot
- If you have had blood in your urine, it may lead to urinary tract obstruction.
- If you have blood clots or a history of medical problems caused by a blood clotting disease or bleeding from an area in your brain
- If you have colour vision problems
- If you have liver problems
- If you have kidney problems
- If you have a history of convulsions

If you think any of these apply to you, or if you are in any doubt at all, tell your doctor before CYKLOCLOT is given to you.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have had blood in your urine, it may lead to urinary tract obstruction.
- If you have a risk of having blood clots.
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation), CYKLOCLOT may not be right for you, except if you have acute severe bleeding and blood test have shown the process that inhibits blood clotting called fibrinolysis is activated.
- If you have had convulsions, CYKLOCLOT should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with CYKLOCLOT.



- If you are on a long-term treatment with CYKLOCLOT, attention should be paid to possible disturbances of colour vision and if necessary, the treatment should be discontinued. With continuous long-term use of CYKLOCLOT, regular ophthalmologic examinations (eye examinations including visual acuity, colour vision, fundus, visual field etc.) are indicated. With pathological ophthalmic changes, particularly with diseases of the retina, your doctor must take a decision after consulting a specialist on the necessity for the long-term use of CYKLOCLOT in your case.

Other medicines and CYKLOCLOT

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

You should specifically tell them if you take:

- other medicines that help blood to clot called antifibrinolytic medicines
- medicines that prevent blood clotting, called thrombolytic medicines
- oral contraceptives

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking this medicine.

If you are a woman of childbearing potential, you must use effective contraceptives.

Tranexamic acid is excreted in human milk. Therefore, the use of CYKLOCLOT during breastfeeding is not recommended.



Driving and using machines

It is not always possible to predict to what extent CYKLOCLOT may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which CYKLOCLOT affects you.

3. How to use CYKLOCLOT

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

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

CYKLOCLOT will be given to you by slow injection or infusion into a vein.

Your doctor will decide the correct dose for you and how long you should receive it.

If you have the impression that the effect of CYKLOCLOT is too strong or too weak, tell your doctor or pharmacist.

If you receive more CYKLOCLOT than you should

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

If you missed a dose of CYKLOCLOT

Since a health care provider will administer CYKLOCLOT, it is unlikely that the dose will be missed.

4. Possible side effects

CYKLOCLOT can have side effects.

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



If any of the following happens, stop using CYKLOCLOT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and 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 reaction to CYKLOCLOT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- nausea,
- vomiting,
- diarrhoea.

Less frequent

- skin rash.

Frequency unknown

- dizziness,
- malaise with hypotension (low blood pressure), with or without loss of consciousness, especially if the injection is given too quickly,
- blood clots,
- convulsions (fits),
- vision disturbances including impaired colour vision,
- allergic reactions.



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 “**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**”, found online under SAHPRA’s publications:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf

By reporting side effects, you can help provide more information on the safety of CYKLOCLOT.

5. How to store CYKLOCLOT

Store all medicines out of reach of children.

- Store at or below 30 °C
- Do not freeze
- Keep the container in the outer carton
- CYKLOCLOT is for single use only
- Do not use after the expiry date stated on the label/ 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 CYKLOCLOT contains

- The active substance is tranexamic acid. Each 5 ml of solution contains 500 mg of tranexamic acid.
- The other ingredient is: Water for injection.

What CYKLOCLOT looks like and contents of the pack

CYKLOCLOT is a clear, colourless solution.



It is packed as 5 ml in USP type I clear glass ampoule.

Pack size: 1 ampoule in an outer carton.

Holder of Certificate of Registration

Kahma Biotech (Pty) Ltd

106, 16th Road

Midrand

This leaflet was last revised in

7 February 2023

Registration number

540866

Access to the corresponding Professional Information

To follow

A handwritten signature in black ink, consisting of stylized initials 'R' and 'L'.