

SCHEDULING STATUS

S4

TRANEXAMIC ACID 100 mg/mL PHARMC solution for injection

Tranexamic acid

Sugar free

Read all of this leaflet carefully before you are given TRANEXAMIC ACID 100 mg/mL PHARMC

- 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 TRANEXAMIC ACID 100 mg/mL PHARMC is and what it is used for.
2. What you need to know before you are given TRANEXAMIC ACID 100 mg/mL PHARMC.
3. How to receive TRANEXAMIC ACID 100 mg/mL PHARMC.
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5. How to store TRANEXAMIC ACID 100 mg/mL PHARMC.
6. Contents of the pack and other information.

1. What TRANEXAMIC ACID 100 mg/mL PHARMC is and what it is used for

TRANEXAMIC ACID 100 mg/mL PHARMC contains tranexamic acid which belongs to the class of medicines called antifibrinolytics.

TRANEXAMIC ACID 100 mg/mL PHARMC is used for a short period of time to prevent or reduce bleeding in certain conditions:

- Prostate or bladder surgery
- Nose bleeds (epistaxis)
- Abnormalities of the cervix
- Bleeding inside the eye (hyphaema)
- Tooth removal (dental extraction) in haemophiliacs
- A hereditary disease called angioedema
- Heavy periods/ severe menstrual bleeding (menorrhagia)

2. What you need to know before you are given TRANEXAMIC ACID 100 mg/mL PHARMC

TRANEXAMIC ACID 100 mg/mL PHARMC should not be administered to you

- If you are hypersensitive (allergic) to tranexamic acid or any of the other ingredients of TRANEXAMIC ACID 100 mg/mL PHARMC (listed in section 6).
- If you have massive bleeding in the upper urinary tract (bladder and kidney area).
- If you currently have a disease leading to blood clots.
- If you have colour vision disorder.
- If you have inflammation of the wall of a vein with associated blood clotting (thrombophlebitis).
- If you have liver problems.
- If you have bleeding into the space surrounding the brain.
- If you have a condition called 'consumption coagulopathy' where blood in the whole body starts to clot.
- 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 TRANEXAMIC ACID 100 mg/mL PHARMC is given to you.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- If you have had convulsions. Your doctor might use the lowest dose possible to avoid convulsions after your treatment with TRANEXAMIC ACID 100 mg/mL PHARMC.
- If you are using TRANEXAMIC ACID 100 mg/mL PHARMC over a long period of time, you may have a higher risk to become colour blind. Your doctor might test your eyes regular and based on the results decide to stop treatment.
- 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 a risk of having blood clots and/or if you are receiving Factor IX Complex Concentrates or Anti-inhibitor Coagulant Concentrates. TRANEXAMIC ACID 100 mg/mL PHARMC may increase your risk of blood clotting.
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation). Your doctor will decide if TRANEXAMIC ACID 100 mg/mL PHARMC is right for you.
- If you have heavy periods/ severe menstrual bleeding (menorrhagia), your doctor might do some blood tests to make sure why you have menorrhagia before TRANEXAMIC ACID 100 mg/mL PHARMC is given to you.

Other medicines and TRANEXAMIC ACID 100 mg/mL PHARMC

Always tell your healthcare provider if you are taking any other medicine. (This includes 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 and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before using TRANEXAMIC ACID 100 mg/mL PHARMC.

Women that can become pregnant have to use effective contraception during TRANEXAMIC ACID 100 mg/mL PHARMC treatment. Tranexamic acid as in TRANEXAMIC ACID 100 mg/mL PHARMC passes into breastmilk. Therefore, you should not use TRANEXAMIC ACID 100 mg/mL PHARMC when you are breastfeeding.

Driving and using machines

It is not always possible to predict to what extent TRANEXAMIC ACID 100 mg/mL PHARMC may interfere with your daily activities. TRANEXAMIC ACID 100 mg/mL PHARMC may cause side effects, such as dizziness and vision problems. You should ensure that you do not engage in the above activities until you are aware of the measure to which TRANEXAMIC ACID 100 mg/mL PHARMC affects you.

3. How to receive TRANEXAMIC ACID 100 mg/mL PHARMC

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

You will not be expected to give yourself TRANEXAMIC ACID 100 mg/mL. It will be given to you by a person who is qualified to do so.

Tranexamic acid 100 mg/ml PharmC 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.

Use in children

Data on efficacy and safety in children are limited, and TRANEXAMIC ACID 100 mg/mL should therefore not be used in children.

If you have the impression that the effect of TRANEXAMIC ACID 100 mg/mL is too strong or too weak, tell your doctor or pharmacist.

If you received more TRANEXAMIC ACID 100 mg/mL PHARMC than you should

Since a healthcare professional will administer TRANEXAMIC ACID 100 mg/mL PHARMC, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of TRANEXAMIC ACID 100 mg/mL PHARMC

Since a healthcare professional will administer TRANEXAMIC ACID 100 mg/mL PHARMC, it is unlikely that the dose will be missed.

4. Possible side effects

TRANEXAMIC ACID 100 mg/mL PHARMC can have side effects.

Not all side effects reported for TRANEXAMIC ACID 100 mg/mL PHARMC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRANEXAMIC ACID 100 mg/mL PHARMC please consult your health care provider for advice.

If any of the following happens, stop using TRANEXAMIC ACID 100 mg/mL PHARMC 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 TRANEXAMIC ACID 100 mg/mL PHARMC. 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

Frequent

- nausea
- vomiting
- diarrhoea

Less frequent

- allergic skin reactions
- thromboembolic events (e.g. formation of a blood clot)
- vision disturbances including impaired colour vision

Frequency unknown

- malaise with hypotension (low blood pressure), with or without loss of consciousness, especially if the injection is given too quickly
- blood clots

- convulsions (fits)
- dizziness
- 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. This includes any possible side effects not listed in this leaflet. 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 TRANEXAMIC ACID 100 mg/mL PHARMC

5. How to store TRANEXAMIC ACID 100 mg/mL PHARMC

Store all medicines out of reach of children.

- Store at or below 25 °C
- Keep the container in the outer carton
- TRANEXAMIC ACID 100 mg/mL PHARMC 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 TRANEXAMIC ACID 100 mg/mL PHARMC contains

- The active substance is tranexamic acid. Each 5 ml of solution contains 500 mg of tranexamic acid.
- The other ingredients are hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injection.

What TRANEXAMIC ACID 100 mg/mL PHARMC looks like and contents of the pack

TRANEXAMIC ACID 100 mg/mL PHARMC is a clear, colourless solution. It is packed as 5 ml in USP type I clear glass ampoule. Pack size: 1 or 5 ampoule(s) in an outer carton.

Holder of Certificate of Registration

Pharmacorp (Pty) Ltd

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

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Access to the corresponding Professional Information

For the professional information, refer to the SAHPRA website