

Patient information leaflet for

TRANMENXIO IV

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TRANMENXIO IV, 500 mg/ 5 ml solution for injection

Tranexamic acid

Sugar free

Read all of this leaflet carefully before you are given TRANMENXIO IV. Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor, pharmacist or other health care provider.

What is in this leaflet

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

1. What TRANMENXIO IV is and what it is used for

The name of your medicine is TRANMENXIO IV. TRANMENXIO IV contains a medicine called tranexamic acid. This belongs to a group of medicines called coagulants, antihæmorrhagics, antifibrinolytics.

Specific indications include:

- Blood inside the front chamber of eye,
- Hereditary angioedema, a genetic form of relapsing subcutaneous or submucosal edema.

Patient information leaflet for**TRANMENXIO IV****2. What you need to know before you use TRANMENXIO IV**

Do not take TRANMENXIO IV if:

- If you are allergic to tranexamic acid or any of the other ingredients of TRANMENXIO IV.
- If you have currently a disease leading to blood clots in your blood vessels (arteries or veins).
- If you have a condition called 'consumption coagulopathy' where blood in the whole body starts to clot,
- If you have a history of convulsions (fits),
- If you have a massive upper urinary tract bleeding episode,
- If you have known or pronounced tendency of clotting of the blood in a part of circulatory system,
- If you have known or pronounced disturbances in your colour vision,
- If you suffer from thrombophlebitis (swelling/inflammation of a vein caused by a blood clot),
- If you have impaired liver function,
- If you have bleeding into the subarchnoid space - the area between the archnoid membrane and the pia matter surrounding the brain,

Do not have TRANMENXIO IV if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before you are given TRANMENXIO IV.

Warnings and Precautions

You should receive TRANMENXIO IV through a very slow intravenous injection, and never by intramuscular route.

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

- If you have had convulsions (fits). Your doctor will use the minimum dose possible to avoid further convulsions after the treatment,
- If you are on a long-term treatment with TRANMENXIO IV, attention should be paid to possible disturbances of colour vision and if necessary, the treatment should be stopped.
- With continuous long-term use of TRANMENXIO IV longer than several days regular ophthalmologic

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examinations (eye examinations including visual acuity, colour vision, fundus, visual field etc.), are indicated.

- If you are diagnosed with a disease of the retina. As the doctor will have to decide on the necessity of the long-term use of TRANMEXIO IV.
- If you have a known family history of risk of having blood clots, or previous history of a blood clot, TRANMEXIO IV treatment should be given only if absolutely necessary under strict medical supervision, and should not be given unless simultaneous with anticoagulants,
- if you have had blood in your urine, which could indicate that there is a clot in your upper urinary tract,
- If you have kidney failure, as you doctor will use it with the utmost caution, should therapy be required
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation, or DIC) as tranexamic acid may not be right for you,
- If you are a haemophiliac (have a hereditary bleeding condition), you should not be receiving TRANMEXIO IV at the same time as with Factor IX Complex Concentrates (medication made up of blood clotting factors used to treat and prevent bleeding in haemophilia) or Anti-inhibitor Coagulant Concentrates (medication to control bleeding in haemophilia), as the risk of clotting (thrombosis) may be increased.
- If you are currently on oral contraceptives, due to the risk of blood clotting.
- If you are on treatment to help your blood clot
- If you are on treatment that prevents blood clotting
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

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

This is because tranexamic acid can affect the way some other medicines work. Also, some medicines can affect the way that tranexamic acid works.

You should specifically tell your doctor if you take:

- other medicines that help blood to clot called antifibrinolytic medicines
- medicines that prevent blood clotting, called thrombolytic medicines
- oral contraceptives and hormone replacement therapy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking TRANMEXIO IV.

Tranexamic acid is excreted in human milk. Therefore, the use of TRANMEXIO IV injection during breast-feeding is not recommended.

Driving and using machines

No studies have been performed on the ability to drive and use machines. TRANMEXIO IV may cause side effects such as dizziness and vision problems, that may affect your ability to drive a vehicle and use machines. Do not drive a vehicle, operate machinery, or do anything that requires attention until you know how TRANMEXIO IV affects you.

3. How to use TRANMEXIO IV

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

How tranexamic acid is given

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Tranexamic acid injection will be administered to you slowly (over a period of at least five minutes) into a vein.

How much tranexamic acid is given

Your doctor will determine the dosage and administer it.

Your doctor will tell you how long treatment with TRANMEXIO IV will last. If you have the impression that the effect of TRANMEXIO IV is too strong or too weak, tell your doctor or pharmacist.

Use in patients with kidney problem

If you have kidney problems, your dose may be reduced. Your doctor will decide what dose to give you based on a blood test.

If you take more TRANMEXIO IV than you should

Since a health care provider will administer TRANMEXIO IV, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use TRANMEXIO IV

Since a healthcare professional will administer this medicine, it is unlikely that the dose will be missed.

4. Possible side effects

TRANMEXIO IV can have side effects.

Not all side effects reported for TRANMEXIO IV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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If any of the following happens after you have received TRANMENXIO IV, go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TRANMENXIO IV. 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:

- Hypotension (low blood pressure), with or without loss of consciousness
- blood clots
- convulsions (fits)
- Vision disturbances including impaired colour vision
- diarrhoea, nausea and vomiting

These are all serious side effects. You may need urgent medical attention.

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Tell your doctor if you notice any of the following:

Frequent side effects

- effects on the stomach and intestines: nausea, vomiting, diarrhoea

Less frequent side effects

- effects on the skin problems: rash
- malaise (a general feeling of discomfort, illness, or unease whose exact cause is difficult to identify) with hypotension (low blood pressure), with or without loss of consciousness, especially if the injection is given too quickly
- blood clots
- effects on the nervous system: convulsions (fits), dizziness
- effects on the eyes: vision disturbances including impaired colour vision, Retinal/artery occlusion which is the blockage of the retinal artery carrying oxygen to the nerve cells in the retina, resulting in severe loss of vision
- effects on the immune system: severe 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 or pharmacist. You can also report side effects 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>.

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

5. How to store TRANMEXIO IV

Store at or below 25 °C.

Keep this medicine out of the sight and reach of children.

Use immediately after opening. Discard any unused portion.

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6. Contents of the pack and other information

What TRANMENXIO IV contains

Each 5 ml ampoule contains 500 mg Tranexamic acid.

Sugar free.

The other ingredients are Water for Injection.

What TRANMENXIO IV looks like and contents of the pack

Clear, colourless, solution for injection.

It is packed in a 5 ml Type I clear glass ampoule.

Pack size: Box of 5 ampoules.

Holder of certificate of registration

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