

Patient Information Leaflet

PATIENT INFORMATION LEAFLET

CYNEX 500 mg INJECTION should only be administered intravenously and should not be administered intrathecally or epidurally. In order to reduce the risk of fatal medication errors due to incorrect route of administration of CYNEX 500 mg INJECTION, it is strongly recommended to label the syringes containing CYNEX 500 mg INJECTION.

SCHEDULING STATUS

S4

CYNEX 500 mg INJECTION, solution for injection

Tranexamic acid

Sugar free

Read all of this leaflet carefully before you are given CYNEX 500 mg INJECTION.

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

What is in this leaflet:

1. What CYNEX 500 mg INJECTION is and what it is used for
2. What you need to know before CYNEX 500 mg INJECTION is administered
3. How CYNEX 500 mg INJECTION is administered
4. Possible side effects
5. How to store CYNEX 500 mg INJECTION
6. Contents of the pack and other information...
1. **What CYNEX 500 mg INJECTION is and what it is used for**

CYNEX 500 mg INJECTION contains tranexamic acid which forms part of a group of medicines called antihemorrhagics; antifibrinolytics, amino acids, which is used for the prevention and treatment of bleeding due to a process that inhibits blood clotting called fibrinolysis.

CYNEX 500 mg INJECTION is used to reduce bleeding for a short period of time. You may have been prescribed it for one of the following:

- Prostate.
- Bladder surgery.

2. What you need to know before CYNEX 500 mg INJECTION is administered

CYNEX 500 mg INJECTION should not be administered to you:

- If you are hypersensitive (allergic) to tranexamic acid or any of the other ingredients of CYNEX 500 mg INJECTION (listed in section 6).
- If you have abnormal colour vision or pronounced clotting tendency.
- If you experience massive upper urinary tract bleeding.
- If you have a tendency or a history of developing blood clots.
- If you have a condition in which a blood clot in a vein causes pain and inflammation (thrombophlebitis).
- If you have a condition affecting the ability of your blood to clot and thereby stop bleeding.
- If you suffer from a liver disorder.
- If you suffer from an abnormal and very dangerous condition in which blood collects beneath a membrane that covers the brain.
- If you are pregnant or breastfeeding (see section 2, "Pregnancy and breastfeeding").

Due to the risk of seizures and brain swelling, CYNEX 500 mg INJECTION must not be given into the spine, epidurally (around the spinal cord) or into the brain

Warnings and precautions:

CYNEX 500 mg INJECTION is ONLY to be given to you through a vein either by intravenous infusion (IV) or intravenous injection (IV push). Serious harms have been reported when CYNEX 500 mg INJECTION was given into the spine (intrathecal use). If you notice any pain in your back or legs

during, or soon after this medicine is given, tell your health care provider immediately.

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

- If you have a kidney disorder, you should receive lower doses.
- If you do not know why you suffer from menorrhagia (heavy menstrual bleeding or bleeding that lasts longer than 7 days), the cause for menorrhagia should first be established.
- If you have had seizures (convulsions or fits).
- If you are receiving CYNEX 500 mg INJECTION for a long period of time (you should undergo regular eye examinations).
- If you have blood in your urine, it may lead to urinary tract obstruction.
- If you have ever had any uncontrollable bleeding.
- If you suffer from excessive clotting or bleeding throughout your body (disseminated intravascular coagulation). Your doctor may carry out a blood test to see if the process that inhibits blood clotting (called fibrinolysis) is activated.
- If you are at risk of having blood clots.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Children and adolescents

Do not give CYNEX 500 mg Injection to children because data on efficacy and safety is limited.

Other medicines and CYNEX 500 mg INJECTION:

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

The following medicines may interact with CYNEX 500 mg INJECTION:

- Medicines that help blood to clot, such as antifibrinolytic medicines.
- Thrombolytic medicines (medicines that prevent blood clotting) may oppose the action of CYNEX 500 mg INJECTION.
- Certain hormones (oestrogens) may increase the potential for developing blood clots.

Pregnancy and breastfeeding:

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 receiving CYNEX 500 mg INJECTION.

You should not receive CYNEX 500 mg INJECTION if you are pregnant or breastfeeding.

If you are a woman of child-bearing age, ask your doctor or pharmacist to ensure you are using effective contraception.

Driving and using machines:

It is not always possible to predict to what extent CYNEX 500 mg INJECTION may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CYNEX 500 mg INJECTION affects them.

CYNEX 500 mg INJECTION contains sodium:

This medicine contains less than 1 mmol sodium (23 mg) per unit volume, that is to say it is essentially sodium free.

3. How CYNEX 500 mg INJECTION will be administered

You will not be expected to give yourself CYNEX 500 mg INJECTION. It will be given to you by a person who is qualified to do so, as a slow intravenous infusion/injection over a period of at least five minutes. Administration by injection is usually changed to oral administration after a few days.

Your doctor will decide the correct dose to obtain the results needed. The dose of CYNEX 500 mg INJECTION will be different in each patient depending on your condition and body weight.

Your doctor will tell you how long the treatment will last.

The dose will be reduced if you have kidney disease.

If you have the impression that the effect of CYNEX 500 mg INJECTION is too strong or too weak, tell your doctor or pharmacist.

If you receive more CYNEX 500 mg INJECTION than you should:

Since a health care provider will administer CYNEX 500 mg INJECTION, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you forget to receive CYNEX 500 mg INJECTION:

Since a health care provider will administer CYNEX 500 mg INJECTION, it is unlikely that the dose will be missed.

4. Possible side effects

CYNEX 500 mg INJECTION may have side effects.

Not all side effects reported for CYNEX 500 mg INJECTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CYNEX 500 mg INJECTION, please consult your health care provider for advice.

If any of the following happens, stop receiving CYNEX 500 mg INJECTION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your 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 allergic reaction to CYNEX 500 mg INJECTION. 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:

- Blood clotting complications (such as swelling, redness, warmth and pain in arms and legs).

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:

- Eye disturbances (such as colour disturbances or blurred vision).
- Nausea (feeling sick), vomiting (being sick), diarrhoea.

Less frequent side effects:

- Low blood pressure manifested as light-headedness, dizziness, or even fainting.

Frequency unknown:

- Seizures (convulsions or fits).

If you notice any side effects not mentioned in the 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CYNEX 500 mg INJECTION.

Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000

5. How to store CYNEX 500 mg INJECTION

Store at or below 30 °C.

Protect from light. Do not refrigerate.

Keep the ampoules in the outer carton until required for use.

For single use only. Discard any unused portion.

Do not use CYNEX 500 mg INJECTION after the expiry date on the carton.

Return all unused medicine to the pharmacy for disposal.

Do not dispose of unused medicine in your drains or sewerage systems (e.g. toilets).

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

6. Contents of the pack and other information

What CYNEX 500 mg INJECTION contains:

The active substance is tranexamic acid.

Each 5 mL ampoule contains 500 mg tranexamic acid.

The other ingredients are hydrochloric acid, sodium hydroxide and water for injection.

What CYNEX 500 mg INJECTION looks like and contents of the pack:

Clear, colourless liquid, free from visible particles.

Contents of the pack:

5 mL clear, colourless USP type-I OPC glass ampoule with a blue dot and three brown band.

Pack size:

Five ampoules are packed into a plastic tray, which is packed in an outer carton.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

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Stormill, Ext. 1, Roodepoort

Johannesburg 1724

Tel. no.: +27 (0) 12 643 2000

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Access to the corresponding PIL translation: The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: <https://sunpharma.com/south-africa-products/>

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