TRANEXAMIC ARX

Consumer Medicine Information (CMI) Summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given TRANEXAMIC ARX?

TRANEXAMIC ARX contains the active ingredient tranexamic acid. TRANEXAMIC ARX is used to reduce bleeding and the need for blood transfusions in patients undergoing heart surgery, total knee replacement and total hip replacement surgery.

For more information, see Section 1. Why am I being given TRANEXAMIC ARX? in the full CMI.

2. What should I know before I am given TRANEXAMIC ARX?

Do not use if you have ever had an allergic reaction to tranexamic acid or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given TRANEXAMIC ARX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRANEXAMIC ARX and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How am I given TRANEXAMIC ARX?

- Your doctor will determine the dose that you will be given, based on your weight.
- The dose used in children undergoing heart surgery may be different to the dose used in adult heart surgery.
- The dose may vary depending on whether you suffer from diseases relating to the kidneys.
- TRANEXAMIC ARX is given as an injection or infusion (drip) into a vein.

More instructions can be found in Section 4. How am I given TRANEXAMIC ARX? in the full CMI.

5. What should I know while being given TRANEXAMIC ARX?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you have been given TRANEXAMIC ARX. • If you start on any new medicine, tell your doctor, dentist or pharmacist that you have been administered TRANEXAMIC ARX.
Looking after your medicine	• TRANEXAMIC ARX injection will normally be stored in a hospital. • The undiluted product should be stored in a cool, dry place where the temperature stays below 25°C. It should not be frozen and should be protected from light. • If storage of the diluted solution is necessary, it should be stored at 2°C-8°C for a maximum of 24 hours.

For more information, see Section 5. What should I know while being given TRANEXAMIC ARX? in the full CMI.

6. Are there any side effects?

Common side effects include nausea, vomiting and diarrhoea.

Serious side effects include irregular and often rapid heart beat, heart attack, slow or irregular heart beat, dizziness and light headedness, rapid, weak pulse, white skin, sweating, restlessness, loss of consciousness, fainting, rapid, shallow breathing, cold clammy skin and weakness, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing or breathing, slurred speech and loss of speech, low urine output, drowsiness, nausea, vomiting, breathlessness, pain and swelling in the large veins, usually in your legs, severe abdominal pains, bloody stools, unexpected pain, unexpected swelling in your legs or arms, giddiness or dizziness, allergic skin reactions, changes in your eyesight, convulsions, fits or seizures

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

TRANEXAMIC ARX

Active ingredient: tranexamic acid

Consumer Medicine Information (CMI)

This leaflet provides important information about the administration of TRANEXAMIC ARX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TRANEXAMIC ARX.**

Where to find information in this leaflet:

1. Why am I being givenTRANEXAMIC ARX?
2. What should I know before I am given TRANEXAMIC ARX?
3. What if I am taking other medicines?
4. How am I given TRANEXAMIC ARX?
5. What should I know while being given TRANEXAMIC ARX?
6. Are there any side effects?
7. Product details

1.Why am I being given TRANEXAMIC ARX?

TRANEXAMIC ARX contains the active ingredient tranexamic acid. Tranexamic acid is an antifibrinolytic agent that works by slowing the processes that cause bleeding.

TRANEXAMIC ARX is used to reduce bleeding and the need for transfusion of blood in patients undergoing heart surgery, total knee replacement and total hip replacement surgery.

2. What should I know before I am given TRANEXAMIC ARX?

Warnings

You should not be given TRANEXAMIC ARX if:

- you are allergic to tranexamic acid, or any of the ingredients listed at the end of this leaflet.
  Always check the ingredients to make sure you can use this medicine.
- you are being treated for a stroke.
- you are being treated for blood clots in your legs, lungs or anywhere else in your body.
- you have a problem with colour vision that developed after you were born.

Check with your doctor if you:

- or a family member, has ever suffered from blood clots
- take any medicines for any other condition
- have severe bruising
- have kidney disease with or without blood in the urine
- are pregnant or think you may be pregnant
- are breastfeeding or plan to breastfeed
- have irregular periods and the reason is not known
- have ever suffered from convulsions, fits or seizures
- have any other medical conditions
- are allergic to any other medicines, foods or substances

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

There is limited experience of tranexamic acid use in children less than 2 years of age.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with TRANEXAMIC ARX and affect how it works. These include:

- other medicines used to prevent bleeding (including non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or naproxen; tranexamic acid tablets; contraceptives, aminocaproic acid, clotting or coagulant complexes);
- medicines used to thin the blood, including anticoagulants (such as warfarin, heparin, enoxaparin, apixaban, dabigatran, edoxaban, and rivaroxaban) and antiplatelets (such as aspirin, clopidogrel, dipyridamole, prasugrel, and ticagrelor).

Tell your doctor if you are using hormonal contraceptives, as they may increase the risks of side effects.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TRANEXAMIC ARX.

4. How am I given TRANEXAMIC ARX?

How much is given

- Your doctor will determine the dose that you will be given, based on your weight.
- The dose used in children undergoing heart surgery may be different to the dose used in adult heart surgery.
- The dose may vary depending on whether you suffer from diseases relating to the kidneys.

When TRANEXAMIC ARX is given

TRANEXAMIC ARX is given as an injection or infusion (drip) into a vein before and during surgery.

If you use too much TRANEXAMIC ARX

If you think that you have used too much TRANEXAMIC ARX, you may need urgent medical attention. This is however unlikely, as you will be administered this medicine by a doctor or nurse.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**); or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you are administered too much TRANEXAMIC ARX you may have the following symptoms:

- dizziness or headache
- nausea or diarrhoea
- low blood pressure
- convulsions, fits or seizures.

5. What should I know while being given TRANEXAMIC ARX?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you have been given TRANEXAMIC ARX.

If you start on any new medicine, tell your doctor, dentist or pharmacist that you have been administered TRANEXAMIC ARX.

Looking after your medicine

TRANEXAMIC ARX injection will normally be stored in a hospital. The undiluted product should be stored in a cool, dry place where the temperature stays below 25°C. The injection should not be frozen and should be protected from light.

This product does not contain antimicrobial agents. It is for single use in one patient only.

If storage of the diluted solution is necessary, it should be stored at 2°C-8°C for a maximum of 24 hours. Any unused solution should be discarded. Follow the instructions on the carton on how to take care of your medicine properly.

Getting rid of any unwanted medicine

The hospital will normally dispose of unused or expired TRANEXAMIC ARX.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• nausea • vomiting • diarrhoea	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• unexpected pain or swelling in your legs or arms • giddiness or dizziness • allergic skin reactions • changes in your eyesight • convulsions, fits or seizures • low blood pressure from rapid administration of TRANEXAMIC ARX injection. • irregular and often rapid heart beat • heart attack or chest pain • slow or irregular heart beat • cardiogenic shock caused by very low blood pressure. The symptoms are dizziness and light headedness, rapid, weak pulse, white skin, sweating, restlessness, loss of consciousness, fainting, rapid, shallow breathing, cold clammy skin and weakness. • stroke. The symptoms of stroke are numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech. • kidney problems where you pass little or no urine, drowsiness, nausea, vomiting and breathlessness • difficulty breathing • a condition called deep vein thrombosis (DVT). The symptoms of DVT are pain and swelling in the large veins, usually in your legs. DVT may lead to complications such as blood clots in your lungs • bowel infarction caused by a restriction of blood supply to the bowels. You may experience severe abdominal pains and may pass bloody stools.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TRANEXAMIC ARX contains

Active ingredient (main ingredient)	tranexamic acid
Other ingredients (inactive ingredients)	water for injections

TRANEXAMIC ARX ampoules each contains 100 mg/mL tranexamic acid.

Do not take this medicine if you are allergic to any of these ingredients.

What TRANEXAMIC ARX looks like

TRANEXAMIC ARX injection is a clear and colourless solution. It contains 500 mg tranexamic acid /5 mL ampoule, in packs of 5 ampoules. (AUST R 214485).

Who distributes TRANEXAMIC ARX

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

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