

Tranexamic-AFT

Tranexamic acid, Solution for injection

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Tranexamic-AFT. This leaflet answers some common questions about Tranexamic-AFT.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Tranexamic-AFT against the expected benefits it will have for you.

Use Tranexamic-AFT as instructed and follow the advice given in this leaflet. **If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

Keep this leaflet with the medicine. You may need to read it again.

What Tranexamic-AFT is used for

Tranexamic-AFT is used to prevent excessive bleeding in patients with:

- traumatic hyphaema (bleeding into the front part of the eye)
- blood clotting disorders, who are having minor surgery
- heavy periods
- hereditary angioneurotic oedema (periodic swelling of the throat)

It may also be used to reduce bleeding and the need for transfusion of blood in patients undergoing heart surgery, total knee replacement and total hip replacement surgery.

If you have any questions about Tranexamic-AFT or why it has been prescribed for you talk to your doctor, nurse or pharmacist.

How Tranexamic-AFT works

Tranexamic-AFT contains tranexamic acid. Tranexamic acid is an antifibrinolytic that works by slowing the processes that cause bleeding.

Before treatment with Tranexamic-AFT

When Tranexamic-Acid must not be used

Tranexamic-AFT must not be used if you:

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

Do not take Tranexamic-AFT after the expiry date (EXP) printed on the pack. Medicine taken after the expiry date has passed, it may not work as well.

Do not take Tranexamic-AFT if the packaging is torn or shows signs of tampering.

Do not take Tranexamic-AFT to treat any other complaint unless your doctor tells you to.

Before treatment with Tranexamic-AFT

Tell your doctor if you have any of the following:

- you, or someone in your family, has ever suffered from blood clots
- severe bruising
- kidney disease with or without blood in the urine
- are pregnant or think you may be pregnant
- are breastfeeding or plan to breastfeed
- irregular periods and the reason is not known.

Tell your doctor if you have or have ever suffered from convulsion, fits or seizures before you start taking Tranexamic-AFT.

Convulsions, fits or seizures have been reported with Tranexamic-AFT treatment.

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of these things, tell him/her before you start treatment with Tranexamic-AFT.

Do not give this medicine to anyone else even if they have the same condition as you.

Taking other medicines

Tell your doctor about any other medicines you are taking including medicines that you buy without a prescription, in a pharmacy, supermarket or health food shop.

Some medicines may interfere with Tranexamic-AFT. These include:

- other medicines used to prevent bleeding
- medicines used to thin the blood

These medicines may affect the way Tranexamic-AFT works.

Treatment with Tranexamic-AFT

Cardiac Surgery and Total Knee or Hip Replacement Surgery

Tranexamic-AFT will be administered under medical supervision to reduce blood loss during cardiac surgery or during your knee or hip replacement surgery.

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.

If you are given too much Tranexamic-AFT (overdose)

Tranexamic-AFT will be administered under medical supervision so an overdose is unlikely.

Symptoms from taking too much or being given too much Tranexamic-AFT include:

- dizziness
- headache
- nausea
- diarrhoea
- low blood pressure

- convulsions, fits or seizures.

Immediately telephone your doctor or Poisons Information Centre for advice (in Australia telephone 13 11 26, in New Zealand telephone 0800 POISON (0800 764 766) or go to Accident & Emergency at your nearest hospital if you think you or anyone else has taken too much Tranexamic-AFT, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Have Tranexamic-AFT or this leaflet available to give details if needed. Keep telephone numbers for these places handy.

While you are being treated with Tranexamic-AFT

Things you must do

Tell any other doctors, dentists and pharmacists that you are being treated with Tranexamic-AFT.

If you start on any new medicine, tell your doctor, dentist or pharmacist that you are being treated with Tranexamic-AFT.

Side Effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are being treated with Tranexamic-AFT.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- nausea
- vomiting
- diarrhoea.

These are the more common side effects of Tranexamic-AFT. Mostly these are mild and short-lived.

Following cardiac surgery, total knee replacement or total hip replacement surgery, tell your doctor or nurse immediately if you experience any of the following:

- irregular and often rapid heart beat
- heart attack
- 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.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- unexpected pain
- unexpected 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-AFT.

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

Other side effects not listed above may occur in some patients.

Tell your doctor if you notice any other side effects while being treated with Tranexamic-AFT. Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After Treatment with Tranexamic-AFT

Tranexamic-AFT 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. Do not freeze. Protect 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 2-8 °C for a maximum of 24 hours. Any unused solution should be discarded.

Product Description

What it looks like

Tranexamic-AFT is a clear and colourless solution.

Ingredients

The active ingredient in Tranexamic-AFT is tranexamic acid.

Tranexamic-AFT contains 100 mg/mL of tranexamic acid. It also contains Water for Injections. It may also contain hydrochloric acid or sodium hydroxide to adjust to the correct pH.

Pack sizes

Tranexamic-AFT is available as 500 mg/5 mL (AUST R 228946) and 1,000 mg/10 mL (AUST R 228945).

They are available in packs of 1, 5 and 10 ampoules.

Supplier

AFT Pharmaceuticals Pty. Ltd
113 Wicks Road
North Ryde
NSW 2113

This leaflet was prepared on: 19 November 2015