

TRANEXAMIC ACID LU

tranexamic acid

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

Please read this leaflet carefully before you are given TRANEXAMIC ACID LINK injection. This leaflet answers some common questions about TRANEXAMIC ACID LINK.

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 having an administration of TRANEXAMIC ACID LINK against the expected benefits it will have for you.

If you have any concerns about the administration of this medicine, ask your doctor or pharmacist.

Keep this leaflet you may need to read it again.

WHAT TRANEXAMIC ACID LINK IS USED FOR

TRANEXAMIC ACID LINK 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.

HOW TRANEXAMIC ACID LINK WORKS

TRANEXAMIC ACID LINK contains tranexamic acid. Tranexamic acid is an antifibrinolytic that works by slowing the processes that cause bleeding.

BEFORE RECEIVING TRANEXAMIC ACID LINK

When you must not have an administration of it

Do not have an administration of TRANEXAMIC ACID LINK if you have an allergy to TRANEXAMIC ACID LINK or any of the ingredients listed at the end of this leaflet.

Do not have an administration of TRANEXAMIC ACID LINK if you are being treated for a stroke.

Do not have an administration of TRANEXAMIC ACID LINK if you are being treated for blood clots in your legs, lungs or anywhere else in your body.

Do not have an administration of TRANEXAMIC ACID LINK if you have a problem with colour vision that developed after you were born.

Before you are administered it

You must tell your doctor before he/her administers TRANEXAMIC ACID LINK 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.

Convulsions, fits or seizures have been reported with TRANEXAMIC ACID LINK treatment.

Tell your doctor if you have or have ever suffered from convulsion, fits or seizures before you are administered TRANEXAMIC ACID LINK.

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 they administer TRANEXAMIC ACID LINK.

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 ACID LINK. These include:

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

These medicines may affect the way TRANEXAMIC ACID LINK works.

HOW TRANEXAMIC ACID LINK IS ADMINISTERED

Cardiac Surgery and Total Knee or Total 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 (overdose)

Immediately telephone your doctor or Poisons Information Centre for advice (in Australia telephone 13 11 26, or go to Accident & Emergency at your nearest hospital if you think you or anyone else has been administered too much TRANEXAMIC ACID LINK, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Have TRANEXAMIC ACID LINK or this leaflet available to give details if needed.

Keep telephone numbers for these places handy.

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

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

WHILE YOU ARE BEING ADMINISTERED TRANEXAMIC ACID LINK

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you have been administered TRANEXAMIC ACID LINK.

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

SIDE EFFECTS

Tell your pharmacist or doctor as soon as possible if you do not feel well after you are administered TRANEXAMIC ACID LINK.

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 ACID LINK. 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.

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

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 ACID LINK Solution for Injection.

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 after administration of TRANEXAMIC ACID LINK.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

This leaflet was last updated in August 2014.

AFTER ADMINISTRATION OF TRANEXAMIC ACID LINK

Storage

TRANEXAMIC ACID LINK Solution for 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. 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°C-8°C for a maximum of 24 hours. Any unused solution should be discarded.

Disposal

The hospital will normally dispose of unused or expired TRANEXAMIC ACID LINK.

PRODUCT DESCRIPTION

What it looks like

TRANEXAMIC ACID LINK Solution for Injection is a clear and colourless solution.

Ingredients

The active ingredient in TRANEXAMIC ACID LINK is tranexamic acid.

TRANEXAMIC ACID LINK ampoules each contains 100 mg/mL tranexamic acid.

The inactive ingredient is

- Sterile Water for Injections.

Pack sizes

TRANEXAMIC ACID LINK Solution for Injection is available in packs of

- 5 x 5 mL ampoules each containing 500 mg tranexamic acid and 5 mL Water for Injections.

If you want to know more

If you have any questions about your treatment with TRANEXAMIC ACID LINK, ask your doctor or pharmacist.

Supplier

In Australia by

Link Medical Products Pty Ltd
5 Apollo Street
Warriewood NSW 2102

Australian Register Number

Solution for Injection

500 mg/5 mL ampoule - AUST R 214485