

DBL™ Tranexamic Acid Injection

Tranexamic Acid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Tranexamic Acid Injection.

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 receiving DBL™ Tranexamic Acid Injection against the benefits they expect it will have for you.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Keep this leaflet

You may need to read it again.

What DBL™ Tranexamic Acid Injection is used for

DBL™ Tranexamic Acid Injection is used to reduce bleeding and the need for blood transfusion in adults and children undergoing heart surgery, and adults undergoing total knee or hip replacement surgery.

It works by slowing the breakdown of blood clots.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Before you are given DBL™ Tranexamic Acid Injection

When you must not be given it

You must not be given DBL™ Tranexamic Acid Injection if you

- have an allergy to tranexamic acid

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You must not be given it if

- you have a problem with colour vision that developed after you were born
- you have problems associated with blood clots or stroke.

Before you are given it

Tell your doctor if you have or have had any of the following

- kidney problems
- convulsions, fits or seizures.
- you, or someone in your family has ever suffered from stroke or blood clots

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given DBL™ Tranexamic Acid Injection.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from

your pharmacy, supermarket or health food shop.

Some medicines and DBL™ Tranexamic Acid Injection may interfere with each other. These include:

- medicines used to thin the blood
- some medicines used to prevent bleeding.

These medicines may be affected by DBL™ Tranexamic Acid Injection or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How DBL™ Tranexamic Acid Injection is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

DBL™ Tranexamic Acid Injection is administered to prevent blood loss during surgery. It will be administered by a doctor or nurse as an injection or infusion (drip) into a vein.

How much is given

Your doctor will decide what dose you will receive. This depends on the type of surgery and other factors, such as your weight and how well your kidneys are functioning. The dosage for children undergoing heart surgery may be different to the dose used in adults.

If you are given too much (overdose)

As DBL™ Tranexamic Acid Injection is given under medical supervision, it is very unlikely that you will receive too much.

However, if you experience severe side effects after being given this medicine, tell your doctor immediately.

Symptoms from being given too much include

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

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you may have received too much DBL™ Tranexamic Acid Injection.

Ask your doctor if you have any concerns.

While you are using DBL™ Tranexamic Acid Injection

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with DBL™ Tranexamic Acid Injection.

Tell any other doctors, dentists, and pharmacists who treat you that you are being treated with this medicine.

Things to be careful of

Tranexamic acid may cause dizziness and therefore may influence the ability to drive or use machines.

Be careful driving or operating machinery until you know how tranexamic acid affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DBL™ Tranexamic Acid Injection.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- nausea
- vomiting
- diarrhoea.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- irregular, slow or rapid heart beat
- convulsions, fits or seizures
- changes in your eye sight
- dizziness
- heart attack (symptoms of chest pain which may spread to the neck and shoulders)
- kidney problems where you pass little or no urine, drowsiness, nausea, vomiting and breathlessness
- bowel infarction caused by restricted blood supply to the bowel. Symptoms include abdominal pain and diarrhoea
- a condition called deep vein thrombosis (DVT) which is the formation of blood clots in the legs. This can sometimes lead to complications such as blood clots in your lungs. The symptoms may include pain and swelling in the large veins, usually in your legs, and lung complications can cause symptoms of shortness of breath and chest pain
- stroke which can include collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech
- signs of an allergic reaction, such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing

- cardiogenic shock, a serious heart condition caused by very low blood pressure. Symptoms may include rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting
- symptoms of low blood pressure (dizziness, lightheadedness).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using DBL™ Tranexamic Acid Injection

Storage

DBL™ Tranexamic Acid Injection will be stored in the pharmacy or on the ward. Store 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. Any unused product should be discarded

Product description

What it looks like

DBL™ Tranexamic Acid Injection is a clear, colourless solution available in 5mL and 10mL clear glass ampoules.

Each 5mL ampoule contains 500mg of tranexamic acid. It is available in packs of 5 and 10.

Each 10mL ampoule contains 1000mg of tranexamic acid. It is available in packs of 1 and 10.

Not all pack sizes and presentations are distributed in Australia.

Ingredients

DBL™ Tranexamic Acid Injection contains

- 100 mg per mL of tranexamic acid as the active ingredient

It also contains:

- water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

DBL™ Tranexamic Acid Injection is supplied by:

Australian Sponsor:

Hospira Pty Ltd
ABN 13 107 058 328
Level 3
500 Collins St
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

DBL™ Tranexamic Acid Injection is available in the following sizes:

500 mg/5 mL ampoule AUST R 222162

1,000 mg/10 mL ampoule AUST R 222161

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