Consumer Medicine Information

What is in this leaflet

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

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 Zamic against the expected benefits it will have for you.

Use Zamic 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 Zamic injection is used for

Zamic 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.

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

How Zamic works

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

Before taking Zamic

When you must not take it

Do not take Zamic if you have an allergy to Zamic or any of the ingredients listed at the end of this leaflet.

Do not take Zamic if you are being treated for a stroke.

Do not take Zamic if you are being treated for blood clots in your legs, lungs or anywhere else in your body.

Do not take Zamic if you have a problem with colour vision that developed after you were born.

Do not take Zamic after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Zamic if the packaging is torn or shows signs of tampering.

Before you start to take it

You must tell your doctor about all of the following before you start to take Zamic:

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

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 taking Zamic.

Do not give this medicine to any one 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.

These medicines may affect the way Zamic works.

Using Zamic

How to take it

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

They may differ from the information contained in this leaflet.

Cardiac Surgery and Total Knee or Total Hip Replacement Surgery

Your doctor will determine the dose that you will be given, based on yor 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 take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre for advice (in Australia telephone 131126, in New Zealand telephone 03 474 7000) or go to Accident & Emergency at your nearest hospital if you think you or anyone else has taken too much Zamic, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Have Zamic or this leaflet available to give details if needed.

Keep telephone numbers for these places handy.

If you take too much Zamic you may have the following symptoms:

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

While you are taking Zamic

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Zamic.

If you start on any new medicine, tell your doctor, dentist or pharmacist that you are taking Zamic.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Zamic.

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 Zamic. 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 lightheadedness, 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 Zamic 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 while taking Zamic.

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

You may not experience any of them.

After using Zamic

Storage

Zamic tranexamic acid 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.

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

If your doctor or pharmacist tells you to stop taking Zamic or the medicine has passed the expiry date, ask your pharmacist what to do with any medicine that is left over.

Remember: this medicine is for you. Never give it to someone else even if they have the same condition as you.

Product description

What it looks like

Zamic Solution for Injection is a clear and colourless solution.

The active ingredient is tranexamic acid. Each ampoule contains 100 mg/ mL tranexamic acid.

The inactive ingredient is

· water.

Pack sizes

Zamic 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.

Sponsor

Medsurge Healthcare Pty Limited Unit 2, 6-7 Gilda Court MULGRAVE VICTORIA 3170

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