

Package leaflet: Information for the user
MEDSAMIC 100 mg/ml solution for injection
Tranexamic acid

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Medsamic is and what it is used for
2. What you need to know before you are given Medsamic
3. How to use Medsamic
4. Possible side effects
5. How to store Medsamic
6. Contents of the pack and other information

1. What Medsamic is and what it is used for

Medsamic contains tranexamic acid which belongs to a group of medicines called antihaemorrhagics; antifibrinolytics, aminoacids.

Medsamic is used in adults and children above one year of age for the prevention and treatment of bleeding due to a process that inhibits blood clotting called fibrinolysis.

Specific indications include:

- Heavy periods in women
- Gastrointestinal bleeding
- Haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract
- Ear, nose, or throat surgery
- Heart, abdominal, or gynecological surgery
- Bleeding after you have been treated with another medicine to break down blood clots.

2. What you need to know before you are given Medsamic

Do not use Medsamic:

- if you are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6)
- if you have currently a disease leading to blood clots
- if you have a condition called ‘consumption coagulopathy’ where blood in the whole body starts to clot
- if you have kidney problems.
- if you have a history of convulsions.

Due to the risk of seizures and brain swelling, Medsamic must not be given into the spine, epidurally (around the spinal cord) or into the brain.

If you think any of these apply to you, or if you are in any doubt at all, tell your doctor before taking Medsamic.

Warnings and precautions

This medicine is ONLY to be given to you through a vein by intravenous injection (IV push). This medicine must not be given into the spine, epidurally (around the spinal cord) or into the brain. Serious harms have been reported when this medicine was given into the spine (intrathecal use). If you notice any pain in your back or legs during, or soon after this medicine is given, tell your doctor or nurse immediately.

Talk to your doctor before you are given Medsamic.

Tell your doctor if any of these apply to you to help him or her decide if Medsamic is suitable for you:

- If you have had blood in your urine Medsamic may lead to urinary tract obstruction.
- If you have a risk of having blood clots.
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation), Medsamic may not be right for you, except if you have acute severe bleeding and blood test have shown the process that inhibits blood clotting called fibrinolysis is activated.
- If you have had convulsions, Medsamic should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with Medsamic.
- If you are on a long-term treatment with Medsamic, attention should be paid to possible disturbances of colour vision and if necessary the treatment should be discontinued. With continuous long-term use of Medsamic solution for injection, regular ophthalmologic examinations (eye examinations including visual acuity, colour vision, fundus, visual field etc.)

are indicated. With pathological ophthalmic changes, particularly with diseases of the retina, your doctor must take a decision after consulting a specialist on the necessity for the long-term use of Medsamic solution for injection in your case.

Other medicines and Medsamic

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should specifically tell your doctor if you take:

- other medicines that help blood to clot called antifibrinolytic medicines
- medicines that prevent blood clotting, called thrombolytic medicines
- oral contraceptives

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor for advice before taking this medicine.

Tranexmic acid is excreted in human milk. Therefore, the use of Medsamic during breast-feeding is not recommended.

Driving and using machines

No studies have been performed on the ability to drive and use machines.

3. How to use Medsamic

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use in adults

Medsamic solution for injection will be given to you by slow injection into a vein.

Your doctor will decide the correct dose for you and how long you should take it.

Use in children

If Medsamic solution for injection is given to a child above one year of age, the dose will be based on the child's weight. Your doctor will decide the correct dose for the child and how long he/she should take it.

Use in elderly

No reduction in dosage is necessary unless there is evidence of renal failure.

Use in patients with kidney problem

If you have a kidney problem, your dose of tranexamic acid will be reduced according to a test performed on your blood (serum creatinine level).

Use in patients with hepatic impairment

No reduction in dosage is necessary.

Method of administration

Medsamic should only be administered slowly into a vein.

Medsamic must not be injected into a muscle, into the spine, epidurally (around the spinal cord) or into the brain.

If you are given more Medsamic than you should

If you are given more Medsamic than the recommended dose you may experience a transitory blood pressure lowering. Talk to a doctor or pharmacist immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects reported with tranexamic acid are:

The following side effects have been observed with tranexamic acid:

Common (may affect up to 1 in 10 people)

- effects on the stomach and intestines: nausea, vomiting, diarrhoea

Uncommon (may affect up to 1 in 100 people)

- effects on the skin problems: rash

Not known (frequency cannot be estimated from the available data)

- malaise with hypotension (low blood pressure), especially if the injection is given too quickly
- blood clots
- effects on the nervous system: convulsions
- effects on the eyes: vision disturbances including impaired color vision
- effects on the immune system: allergic reactions
- sudden onset kidney problems due to death of the tissue in the outer part of the kidney (acute renal cortical necrosis)

- an allergic reaction that usually recurs at the same site(s) on re-exposure to the medication and may include round or oval patches of redness and swelling of the skin, blistering, and itching (fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

[to be completed nationally]

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Medsamic

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Medsamic contains

- The active substance is tranexamic acid.
Each 1 ml of solution contains 100 mg of tranexamic acid.
Each 5 mL ampoule contains 500 mg of tranexamic acid.
Each 10 mL ampoule contains 1000 mg of tranexamic acid.
- The other ingredients are: water for injection.

What Medsamic looks like and contents of the pack

Clear glass type I ampoules of 5ml capacity. Boxes of 5 ampoules × 5 ml.

Clear glass type I ampoules of 10ml capacity. Boxes of 5 ampoules × 10 ml.

Clear glass type I ampoules of 5ml capacity. Boxes of 10 ampoules × 5 ml.

Clear glass type I ampoules of 10ml capacity. Boxes of 10 ampoules × 10 ml.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in June 2026.