

Package leaflet: Information for the user
Pilexam 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, please ask your doctor or nurse.
- 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 Pilexam is and what it is used for
2. What you need to know before you are given Pilexam
3. How to use Pilexam
4. Possible side effects
5. How to store Pilexam
6. Contents of the pack and other information

1. What Pilexam is and what it is used for

Pilexam contains tranexamic acid which belongs to a group of medicines called antihaemorrhagics; antifibrinolytics, amino acids.

Pilexam 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 Pilexam

Do not use Pilexam:

- 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 a history of convulsions.

Due to the risk of seizures and brain swelling, Pilexam 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 Pilexam.

Warnings and precautions

This medicine is ONLY to be given to you through a vein as 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 shortly after this medicine is given, tell your doctor or nurse immediately.

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

- If you have had blood in your urine it may lead to urinary tract obstruction.
- If you have a risk of having blood clots. The risk of blood clotting events may be increased in patients using contraceptives containing hormones.
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation), Pilexam 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, Pilexam should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with Pilexam.
- If you are on a long-term treatment with Pilexam, attention should be paid to possible disturbances of colour vision and if necessary the treatment should be discontinued. With continuous long-term use of Pilexam, 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 Pilexam in your case.

Other medicines and Pilexam

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 or use:

- other medicines that help blood to clot called antifibrinolytic medicines
- medicines that prevent blood clotting, called thrombolytic medicines
- any contraceptions containing hormones.

Pregnancy, breast-feeding and fertility

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

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

If you are a female in the fertile age, ask your doctor or pharmacist to ensure you are using effective contraception.

Driving and using machines

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

3. How to use Pilexam

Your doctor, nurse or other healthcare provider will give you Pilexam through a slow injection into one of your veins. Do not inject Pilexam yourself. Your doctor will decide the correct dose for you and how long you should take it. You should continue to receive Pilexam for as long as instructed by your doctor. Consult with your healthcare provider if you have any questions regarding Pilexam.

Use in children

If Pilexam is given to a child from one year, the dose will be based on the child's weight. Your doctor will decide the correct dose for the child and for how long he/she should be treated.

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

Pilexam should only be administered slowly into a vein.

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

If you are given more Pilexam than you should

If you are given more Pilexam 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), with or without loss of consciousness, 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 nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below)

[to be completed nationally]

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

5. How to store Pilexam

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 Pilexam contains

- The active substance is tranexamic acid. Each 1ml of solution contains 100 mg of tranexamic acid.
- The other ingredients are: water for injection.

What Pilexam looks like and contents of the pack

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

Medochemie Ltd.

Ampoule Injectable Facility: 48 Iapetou Street, Agios Athanassios Industrial Area, 4101 Agios

Athanassios, Limassol

Cyprus

This leaflet was last revised in 2026-02-23.

Detailed information on this medicine is available on the website of {name of Member State Agency (link)}