

Package leaflet: Information for the patient

Tafixyl 100 mg/m Solution for injection
tranexamic acid

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

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

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 Tafixyl is and what it is used for
2. What you need to know before you take Tafixyl
3. How to take Tafixyl
4. Possible side effects
5. How to store Tafixyl
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1. What Tafixyl is and what it is used for

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

Tafixyl is used in adults and children above 1 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 and throat surgery
- heart, abdominal or gynaecological surgery
- bleeding after you have been treated with another medicine to break down blood clots.

2. What you need to know before you take Tafixyl

Do not take Tafixyl:

- if you are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6).
- if you currently have 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 seizures.

Due to the risk of brain oedema and seizures, intrathecal and intraventricular injection and intracerebral application are not recommended.

If you think any of these apply to you, or if you are not sure, tell your doctor before taking Tafixyl.

Warnings and precautions

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

- if you have had blood in your urine, Tafixyl may lead to urinary tract obstruction.

- if you have a risk of having blood clots.
- if you have excessive clotting or bleeding throughout the body (disseminated intravascular coagulation), Tafixyl may not be right for you, except if you have acute severe bleeding and if the blood tests show the process that inhibits blood clotting called fibrinolysis is activated.
- if you have had seizures, Tafixyl should not be administered. Your doctor must use the lowest dose possible to avoid seizures following treatment with Tafixyl.
- if you are on a long-term treatment with Tafixyl, attention should be paid to possible colour vision disturbances and if necessary the treatment should be discontinued. With continuous long-term use of Tafixyl 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 retina diseases, your doctor must take a decision after consulting a specialist on the need for the long-term use of Tafixyl solution for injection in your case.

Children and adolescents

If Tafixyl solution for injection 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 how long she/he should take it.

Other medicines and Tafixyl

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, vitamins, minerals, herbal medicines or dietary supplements.

You should specifically tell your doctor if you take:

- other medicines that help blood clotting called antifibrinolytic medicines;
- medicines that prevent blood clotting, called thrombolytic medicines;
- oral contraceptives.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, ask your doctor for advice before taking Tafixyl. Tranexamic acid is excreted in human milk. Therefore, the use of Tafixyl during breast-feeding is not recommended.

Driving and using machines

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

Tafixyl contains sodium hydroxide, hydrochloric acid, nitrogen and water for injections.

3. How to use Tafixyl in Adults

Tafixyl 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 Tafixyl solution for injection 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 how long she/he should take it.

Use in elderly

No dose reduction is necessary unless there is evidence of kidney failure.

Use in patients with kidney problems

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

Use in patients with liver impairment

No dose adjustment is required.

Method of administration

Tafixyl should only be administered slowly into a vein.

Tafixyl must not be injected into a muscle.

If you are given more Tafixyl than the recommended dose

If you are given more Tafixyl 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.

Other side effects reported with Tafixyl are:

The following side effects have been observed with Tafixyl

Common (may affect up to 1 in 10 users)

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

Uncommon (may affect 1 to 10 in 1000 users)

- 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 central nervous system: seizures

- effects on the eyes: vision disturbances including impaired colour vision

- effects on the immune system: allergic reactions

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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5. How to store Tafixyl

Store the ampoules in the original package.

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

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

Do not use this medicine if you notice visible signs of deterioration.

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 Tafixyl contains

The active substance is tranexamic acid 500 mg per 5 ml ampoule.

What Tafixyl looks like and contents of the pack

Type I transparent glass ampoule for injections.
A 5 ml ampoule contains 500 mg of tranexamic acid.
A 10 ml ampoule contains 1000 mg of tranexamic acid.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet was last revised in

February 2015