

PACKAGE LEAFLET: Information for the user

TRAXAL

Solution for injection – 500 mg / 5 ml

(Tranexamic acid)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Traxal is and what it is used for
2. Before you take Traxal
3. How to take Traxal
4. Possible side effects
5. How to store Traxal
6. Further information

1. WHAT TRAXAL IS AND WHAT IT IS USED FOR

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

Traxal is used in adults 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. BEFORE YOU TAKE TRAXAL

Do not take Traxal if you:

- are allergic to tranexamic acid, sodium metabisulphite or to any of the other ingredients mentioned in the end of this leaflet (see paragraph 6);
- have currently a disease leading to blood clots;
- have a condition called "consumption coagulopathy" (disseminated intravascular coagulation) where blood in the whole body starts to clot;
- have kidney problems;
- have a history of convulsions.

Due to the risk of cerebral oedema and convulsions, intrathecal and intraventricular injection and intracerebral application are contraindicated.

It is generally contraindicated in pregnancy and breastfeeding.

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

Take special care with Traxal

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

- if you have had blood in urine, because Traxal can lead to obstruction of the urinary tract;
- if you have a risk of having blood clots;
- if you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation), Traxal may not be right for you, except if you have acute severe bleeding and blood tests have shown the process that inhibits blood clotting called fibrinolysis is activated;
- if you have had convulsions, Traxal should not be administered; your doctor must use the minimal dose possible to avoid convulsions following treatment with Traxal;

- if you are on a long-term treatment with Traxal, attention should be paid to possible disturbances of colour vision and if necessary the treatment should be discontinued; with continuous long-term use of Traxal 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 Traxal solution for injection in your case.

Taking other medicines

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 to clot called antifibrinolytic medicines;
- medicines that prevent blood clotting, called thrombolytic medicines;
- oral contraceptives.

Pregnancy and breastfeeding

Ask your doctor for advice if you are pregnant or breastfeeding before taking Traxal.

In general it is contraindicated in pregnancy.

Tranexamic acid is excreted in human milk. Therefore, the use of Traxal during breastfeeding is not recommended.

Driving and using machines

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

Important information about some of the excipients of Traxal

Traxal contains sodium metabisulphite. Sodium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm.

3. HOW TO TAKE TRAXAL

Traxal 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 elderly

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

Use in patients with kidney problems

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

Traxal should only be administered slowly into a vein.

Traxal must not be injected into a muscle.

If you are given more Traxal than you should

If you are given more Traxal 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, Traxal can cause side effects, although not everybody gets them.

Possible side effects are:

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 1,000 users)

- effects on the skin problems: rash.

Unknown (the 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.

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.

5. HOW TO STORE TRAXAL

Keep out of the reach and sight of children!

Do not use Traxal after the expiry date which is stated on the package.

Store below 25°C! Keep in the original package.

6. FURTHER INFORMATION

What Traxal solution for injection contains

The active substance is tranexamic acid.

Each ampoule 5 ml contains 500 mg tranexamic acid.

The other ingredients are: sodium metabisulphite, sodium citrate dihydrate, sodium hydroxide, water for injection.

Content of the pack

Box with 10 ampoules 5 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in December 2023.