

Proposed patient information leaflet for FIBTIN INJECTION

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

FIBTIN INJECTION 500 mg/5 mL solution for injection

Tranexamic acid

Sugar free

Read all of this leaflet carefully before you are given FIBTIN INJECTION

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.

FIBTIN INJECTION has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same.

What is in this leaflet

1. What FIBTIN INJECTION is and what it is used for
2. What you need to know before you use FIBTIN INJECTION
3. How to use FIBTIN INJECTION
4. Possible side effects

5. How to store FIBTIN INJECTION
6. Contents of the pack and other information

1. What FIBTIN INJECTION is and what it is used for

FIBTIN INJECTION contains the active substance tranexamic acid and belongs to a group of medicines called anti-fibrinolytic medicines.

FIBTIN INJECTION is used to prevent or reduce bleeding for a short period of time in many different conditions. You may have been prescribed it for one of the following:

- to treat a defect in your body's mechanism for blood clotting, before undergoing minor surgery or dental extraction;
- to treat bleeding inside your eye (traumatic hyphaema);
- to treat a hereditary disease called angioedema (HANO). A doctor would have told you if you have this; to treat heavy periods (menorrhagia).

2. What you need to know before you use FIBTIN INJECTION

FIBTIN INJECTION should not be administered to you:

- If you have a known hypersensitivity (allergy) to tranexamic acid or any of the other ingredients of FIBTIN INJECTION (see section 6).
- If you have blood in your urine as a result of urinary tract bleeding.
- If you are prone to developing blood clots or have a disorder affecting your colour vision.
- If you have inflammation of a vein as a result of a blood clot (called thrombophlebitis).
- If you have liver problems.
- If you had a stroke causing bleeding in the space between your brain and the tissues

that cover it (subarachnoid space).

- If you have a blood clot in your blood vessels (called a 'thrombosis').
- If you are at risk of excessive bleeding as a result of a bleeding disorder called consumption coagulopathy.
- If you have a history of convulsions.

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

Warnings and precautions

Take special care with FIBTIN INJECTION:

- If you have had convulsions, FIBTIN INJECTION should not be administered. Your doctor must use the minimal dose possible to avoid convulsions following treatment with FIBTIN INJECTION.
- If you are receiving FIBTIN INJECTION for a long time you will need to go for an eye examination. If you experience disturbances with your vision, advise your doctor immediately and FIBTIN INJECTION treatment will be discontinued.
- If you have blood in your urine, it may lead to urinary tract obstruction.
- If you are taking oral contraceptives.
- If you have excessive clotting or bleeding throughout your body (disseminated intravascular coagulation) (DIC). FIBTIN INJECTION 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 or your family have a history of blood clots in your blood vessels (called a 'thrombosis').

- If you have kidney disease.
- If you are being treated with Factor IX Complex Concentrates or Anti-inhibitor Coagulant Concentrates (used to prevent bleeding).
- Patients with very heavy irregular menstrual bleeding should not use FIBTIN INJECTION until the cause of the irregularity has been established.

Other medicines and FIBTIN INJECTION

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently taking:

- Fibrinolytic medicines (used to help dissolve blood clots). This is because FIBTIN INJECTION will stop these medicines from working.
- Oral contraceptives (these may increase the risk of blood clots forming).

FIBTIN INJECTION with food

There are no known interactions between FIBTIN INJECTION and food.

Pregnancy and breastfeeding

The safety and efficacy in pregnancy and breastfeeding have not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving FIBTIN INJECTION.

FIBTIN INJECTION is excreted in breastmilk. You should therefore not receive FIBTIN INJECTION while you are breastfeeding.

If you are a woman, you should use effective contraception during treatment with FIBTIN INJECTION.

Driving and using machines

FIBTIN INJECTION may cause side effects, such as dizziness and vision problems, that may affect your ability to drive a vehicle and use machines (see section 4). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how FIBTIN INJECTION affects you.

3. How to use FIBTIN INJECTION

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself FIBTIN INJECTION. It will be given to you by a person who is qualified to do so.

FIBTIN INJECTION will be given to you by slow injection or infusion into a vein.

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

If you have the impression that the effect of FIBTIN INJECTION is too strong or too weak, tell your doctor or pharmacist.

If you receive more FIBTIN INJECTION than you should

Since a health care provider will administer FIBTIN INJECTION, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use FIBTIN INJECTION

Since a health care provider will administer FIBTIN INJECTION to you, it is unlikely that the dose will be missed. You should not receive a double dose to make up for a forgotten dose.

4. Possible side effects

FIBTIN INJECTION can have side effects.

Not all side effects reported for FIBTIN INJECTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving FIBTIN INJECTION, please consult your health care provider for advice. If any of the following happens, you should stop receiving FIBTIN INJECTION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to FIBTIN INJECTION. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Side effects occurring with unknown frequency:

- convulsions (fits);
- formation of blood clots (unusual pain or swelling in your arms or legs).

These are serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Side effects occurring frequently:

- nausea (feeling sick), vomiting (being sick), diarrhoea.

Side effects occurring with unknown frequency:

- dizziness;
- problems with your eyesight, especially your colour vision;
- general feeling of being unwell, low blood pressure (with or without loss of consciousness), especially if the injection is given too quickly.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of FIBTIN INJECTION.

5. How to store FIBTIN INJECTION

- Store at or below 25 °C.
- Do not freeze.
- Protect from light.
- Keep the ampoules in the outer carton until required for use.
- FIBTIN INJECTION is for single use only. Unused solution must be discarded.
- *After opening:* From a microbiological point of view, FIBTIN INJECTION should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FIBTIN INJECTION contains

The active substance is tranexamic acid.

Each 5 mL ampoule contains 500 mg tranexamic acid.

The other ingredient is water for injection.

What FIBTIN INJECTION looks like and contents of the pack

Clear, colourless solution.

5 x 5 mL Type I clear glass ampoules packed into a PVC tray and enclosed in an outer carton.

10 x 5 mL Type I clear glass ampoules packed into two PVC trays and enclosed in an outer carton.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

28 April 2021

Registration number

48/8.1/0251

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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