BIO-TRANEXAMIC 500

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

BIO-TRANEXAMIC 500 mg film-coated tablets

Tranexamic acid

Sugar free

Read all of this leaflet carefully before you start taking BIO-TRANEXAMIC 500.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- BIO-TRANEXAMIC 500 has been prescribed for you or your child 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 BIO-TRANEXAMIC 500 is and what it is used for
2. What you need to know before you take BIO-TRANEXAMIC 500
3. How to take BIO-TRANEXAMIC 500
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6. Contents of the pack and other information

1. What BIO-TRANEXAMIC 500 is and what it is used for

BIO-TRANEXAMIC 500 contains the active substance tranexamic acid and belongs to a group of medicines called anti-fibrinolytic medicines. These are used to stop or reduce unwanted bleeding. When you bleed your body forms clots to stop the bleeding. In some people these break down causing too much bleeding. BIO-TRANEXAMIC 500 stops these clots dissolving and so reduces unwanted bleeding.

BIO-TRANEXAMIC 500 is used to prevent or reduce bleeding for a short period of time in many different conditions. You or your child 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 will have told you if you have this;
- to treat heavy periods (menorrhagia).

2. What you need to know before you take BIO-TRANEXAMIC 500

Do not use BIO-TRANEXAMIC 500

- if you or your child have a known hypersensitivity (allergy) to tranexamic acid or any of the other ingredients of BIO-TRANEXAMIC 500 (see section 6);
- if you or your child have serious problems with your kidneys;
- if you or your child have or have ever had a blood clot in your blood vessels (called a `thrombosis');
- if you or your child are at risk of excessive bleeding as a result of a bleeding disorder called consumption coagulopathy;
- if you or your child have a history of convulsions;
- if you or your child have bleeding in your upper urinary tract (causing blood in your urine);
- if you or your child have a decreased ability to see colour or differences in colour;
- if you or your child have liver problems;
- if you or your child have bleeding in your brain.

Warnings and precautions

Take special care with BIO-TRANEXAMIC 500

- if you or your child have blood in your urine;
- if you or your child have ever had any uncontrollable bleeding;
- if you or your child have disseminated intravascular coagulation (DIC), a disease where your blood starts to clot throughout your body;
- if you or your child have been taking medicine to treat a hereditary disease called angioedema (HANO) every day for a long time. If so, you may need to have regular eye tests and blood tests to check your liver is working properly;
- if you are a woman with irregular periods;
- if you or your family have a history of blood clots in your blood vessels (called a `thrombosis');
- if you or your child have kidney disease.

Children under the age of 15 years

The safety and efficacy of BIO-TRANEXAMIC 500 for the treatment heavy menstrual bleeding in children under the age of 15 years have not been established.

Other medicines and BIO-TRANEXAMIC 500

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

Tell your doctor or pharmacist if you or your child is currently taking:

- fibrinolytic medicines (used to help dissolve blood clots). This is because BIO-TRANEXAMIC 500 will stop these medicines working;
- oral contraceptives (these may increase the risk of blood clots forming).

BIO-TRANEXAMIC 500 with food

There are no known interactions between BIO-TRANEXAMIC 500 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 taking BIO-TRANEXAMIC 500.

Driving and using machines

BIO-TRANEXAMIC 500 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 BIO-TRANEXAMIC 500 affects you.

3. How to take BIO-TRANEXAMIC 500

Do not share medicines prescribed for you or your child with any other person. Always take or give BIO-TRANEXAMIC 500 exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are unsure.

Use in adults and the elderly:

Your doctor will tell you how many BIO-TRANEXAMIC 500 tablets to take and how long you should continue to take them. The exact dose you take will depend on why you have been prescribed these tablets.

Use in patients with kidney problems:

Your doctor will tell you how much to take. The dose you take may be lower than the usual adult dose.

Your doctor will tell you how long you or your child's treatment with BIO-TRANEXAMIC 500 will last. Do not stop treatment without discussing it with you doctor first. If you have the impression that the effect of BIO-TRANEXAMIC 500 is too strong or too weak, tell your doctor or pharmacist.

If you or your child takes more BIO-TRANEXAMIC 500 than you should

Taking too much BIO-TRANEXAMIC 500 may cause symptoms such as nausea (feeling sick), vomiting (being sick) or dizziness or light-headedness upon standing.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take or give BIO-TRANEXAMIC 500

If you forget to take or give BIO-TRANEXAMIC 500, take or give it as soon as you can.

Take or give the next dose at the usual time.

Do not take or give a double dose to make up for a forgotten dose.

4. Possible side effects

BIO-TRANEXAMIC 500 can have side effects.

Not all side effects reported for BIO-TRANEXAMIC 500 are included in this leaflet. Should your or your child's general health worsen or if you experience any untoward effects while taking BIO-TRANEXAMIC 500, please consult your health care provider for advice. If any of the following happens, stop taking or giving BIO-TRANEXAMIC 500 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 or your child has them, you or your child may have had a serious reaction to BIO-TRANEXAMIC 500. You or your child 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 effect occurring less frequently:

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

This is a serious side effect. You or your child may need urgent medical attention.

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

Side effects occurring less frequently:

- dizziness;
- problems with your eyesight, especially your colour vision;
- nausea (feeling sick), vomiting (being sick), diarrhoea.

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.

By reporting side effects, you can help provide more information on the safety of BIO-TRANEXAMIC 500.

5. How to store BIO-TRANEXAMIC 500

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**.
- Do not use after the expiry date printed on the label/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 BIO-TRANEXAMIC 500 contains

The active substance is tranexamic acid.

Each film-coated tablet contains 500 mg tranexamic acid.

The other ingredients are colloidal anhydrous silica, croscarmellose cellulose, macrogol 8 000, magnesium stearate (E572), methacrylate polymers, microcrystalline cellulose (E460), povidone (E1201), talcum (E553b), titanium dioxide (E171) and vanillin.

What BIO-TRANEXAMIC 500 looks like and contents of the pack

White to off white, film-coated, capsule shaped, biconvex, 18 mm long and 8 mm wide, with a break-line and embossed “TXA 500”.

10 film-coated tablets are packed in one PVC/aluminium blister strip.

PVC/aluminium blister strips are packed in an outer carton box.

Pack sizes:

30 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd

Ground floor, Block K West, Central park

400 16th Road, Randjespark

Midrand 1685

011 848 3050

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