# 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
4. Possible side effects
5. How to store BIO TRANEXAMIC 500
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 healthcare 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 healthcare 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 healthcare 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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# BIO TRANEXAMIC 500

**PASIËNTINLIGTINGSPAMFLET**

**SKEDULERINGSTATUS**

S4

BIO TRANEXAMIC 500 mg filmbedekte tablette
Traneksamiensuur
Suiker vry

**Lees hierdie hele pamflet noukeurig deur voordat jy begin om BIO TRANEXAMIC 500 te neem.**

- Hou hierdie pamflet. Jy mag dit dalk weer moet deurlees.
- Indien jy enige verdere vrae het, vra jou dokter, apteker, verpleegster of ander gesondheidsorg-verskaffer.
- BIO TRANEXAMIC 500 is vir jou of jou kind persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit mag hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

**Wat is in hierdie pamflet**

1. Wat BIO TRANEXAMIC 500 is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy BIO TRANEXAMIC 500 neem
3. Hoe om BIO TRANEXAMIC 500 te neem
4. Moontlike newe-effekte
5. Hoe om BIO TRANEXAMIC 500 te bewaar
6. Inhoud van die pak en ander inligting

**1. Wat BIO TRANEXAMIC 500 is en waarvoor dit gebruik word**

BIO TRANEXAMIC 500 bevat die aktiewe stof traneksamiensuur en behoort aan 'n groep medisyne wat anti-fibrinolitiese medisyne genoem word. Hierdie word gebruik om ongewensde bloeding te stop of te verminder. Wanneer jy bloei, vorm jou liggaam bloedklonte om die bloeding te stop. In sommige mense breek hierdie bloedklonte af wat te veel bloeding veroorsaak. BIO TRANEXAMIC 500 keer dat hierdie klonte oplos en verminder dus ongewenste bloeding.

BIO TRANEXAMIC 500 word gebruik om bloeding te voorkom of verminder vir 'n kort tydperk in menigde toestande. Jy of jou kind mag dit voorgeskryf word vir een van die volgende:

- om 'n defek in jou liggaam se meganisme vir bloedstolling te behandel, voordat jy klein operasies of tandheelkundige ekstraksie ondergaan;
- om bloeding binne in jou oog te behandel (traumatiese hipeem);
- om 'n oorerflike siekte te behandel genaamd angioedeem (HANO). 'n Dokter sou jou vertel het indien jy dit het;
- om swaar menstruasie te behandel (menorragie).

**2. Wat jy moet weet voordat jy BIO TRANEXAMIC 500 neem**
**Moenie BIO TRANEXAMIC 500 neem nie**

- indien jy of jou kind 'n bekende hipersensitiwiteit (allergie) vir traneksamiensuur of vir enige van die ander bestanddele van BIO TRANEXAMIC 500 het (sien afdeling 6);
- indien jy of jou kind ernstige probleme met jul niere het;
- indien jy of jou kind 'n bloedklont in jou bloedvate het of al ooit gehad het (genaamd 'n `trombose');
- indien jy of jou kind die risiko loop om oormatige bloeding te hê as gevolg van 'n bloedingsversteuring genaamd verbruikskoagulopatie;
- indien jy of jou kind 'n geskiedenis het van aanvalle/ stuiptrekkings;
- indien jy of jou kind bloeding in jou boonste urienweg het (wat bloed in jou uriene veroorsaak);
- indien jy of jou kind 'n verminderde vermoë het om kleur of verskille in kleur te sien;
- indien jy of jou kind lewerprobleme het;
- indien jy of jou kind bloeding in jou brein het.

**Waarskuwings en voorsorgmaatreëls**
**Neem spesiale sorg met BIO TRANEXAMIC 500**

- indien jy of jou kind bloed in jul uriene het;
- indien jy of jou kind onbeheerde bloeding het of al ooit gehad het;
- indien jy of jou kind verspreide intravaskulêre koagulasie (DIC), 'n siekte waar jou bloed deur jou hele liggaam begin stol;
- indien jy of jou kind vir 'n lang tyd elke dag medisyne gebruik om 'n oorerflike siekte genaamd angioedeem (HANO) te behandel. Indien wel, sal jy dalk gereeld oogtoetse en bloedtoetse moet ondergaan om te kyk of jou lewer behoorlik werk;
- indien jy 'n vrou is met ongereelde menstruasieperiodes;
- indien jy of jou familie 'n geskiedenis van bloedklonte in jul bloedvate het (genaamd 'trombose');
- indien jy of jou kind niersiektes het.

**Kinders jonger as 15 jarige ouderdom**

Die veiligheid en doeltreffendheid van BIO TRANEXAMIC 500 vir die behandeling van swaar menstruele bloeding in kinders jonger as 15 jarige ouderdom is nog nie vasgestel nie.

**Ander medisyne en BIO TRANEXAMIC 500**

Vertel altyd jou gesondheidsorgverskaffer indien jy of jou kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Vertel jou dokter of apteker indien jy of jou kind tans die volgende neem:

- fibrinolitiese medisyne (gebruik om bloedklonte te help oplos). Dit is omdat BIO-TRANEXAMIC 500 sal veroorsaak dat hierdie medisyne ophou werk;
- orale voorbehoedingspille (hierdie mag die risiko van bloedklont formasie verhoog).

**BIO TRANEXAMIC 500 met kos**

Daar is geen bekende interaksies tussen BIO TRANEXAMIC 500 en voedsel nie.

**Swangerskap en borsvoeding**

Die veiligheid en doeltreffendheid in swangerskap en borsvoeding is nog nie vasgestel nie. Indien jy swanger is of borsvoed, dink dat jy dalk mag swanger wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy BIO TRANEXAMIC 500 neem.

**Bestuur en die gebruik van masjiene**

BIO TRANEXAMIC 500 mag newe-effekte veroorsaak soos duiseligheid en visieprobleme wat jou vermoë om 'n voertuig te bestuur en masjiene te gebruik beïnvloed (sien afdeling 4). Moenie 'n motor bestuur of masjinerie gebruik of enige iets anders doen wat jou aandag verg totdat jy weet hoe BIO TRANEXAMIC 500 jou affekteer nie.

**3. Hoe om BIO TRANEXAMIC 500 te neem**

Moenie medisyne wat vir jou of jou kind voorgeskryf is met enige ander persoon deel nie. Neem of gee altyd BIO TRANEXAMIC 500 presies soos jou dokter of apteker jou opdrag gegee het. Raadpleeg jou dokter of apteker indien jy nie seker is nie.

**Gebruik in volwassenes en die bejaardes:**

Jou dokter sal jou vertel hoeveel BIO TRANEXAMIC 500 tablette om te neem en vir hoe lank jy moet aanhou om dit te neem. Die presiese dosis wat jy neem sal afhang van hoekom jy hierdie tablette vir jou voorgeskryf is.

**Gebruik in pasiënte met nierprobleme:**

Jou dokter sal jou vertel hoeveel om te neem. Die dosis wat jy neem mag laer wees as die gewone volwasse dosis.

Jou dokter sal jou vertel hoe lank jou of jou kind se behandeling met BIO TRANEXAMIC 500 sal duur. Moenie die behandeling staak sonder om dit eers met jou dokter te bespreek nie. Indien jy die indruk het dat die effek van BIO TRANEXAMIC 500 te sterk of te swak is, vertel jou dokter of apteker.

**Indien jy of jou kind meer BIO TRANEXAMIC 500 neem as wat jy/ hulle moet**

Die neem van te veel BIO TRANEXAMIC 500 mag simptome soos naarheid (siek gevoel), braking (siek wees) of duiseligheid of lighoofdigheid veroorsaak wanneer jy opstaan.

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

**Indien jy vergeet om BIO TRANEXAMIC 500 te neem of te gee**

Indien jy vergeet om BIO TRANEXAMIC 500 te neem of te gee, neem of gee dit so gou as wat jy kan.

Neem of gee die volgende dosis op die gewone tyd.

Moenie 'n dubbele dosis neem of gee om op te maak vir 'n vergete individuele dosis nie.

**4. Moontlike newe-effekte**

BIO TRANEXAMIC 500 kan newe-effekte hê.

Nie al die newe-effekte wat vir BIO TRANEXAMIC 500 aangemeld is word in hierdie pamflet bevat nie. Sou jou of jou kind se algemene gesondheidstoestand versleg of indien jy enige ongewensde effekte ervaar terwyl jy BIO TRANEXAMIC 500 neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies/ raad. Indien enige van die volgende gebeur, hou op om BIO TRANEXAMIC 500 te neem of te gee en vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel wat moeilike sluk of moeilike asemhaling mag veroorsaak;
- veluitslag of jeuk;
- floute.

Hierdie is almal baie ernstige newe-effekte. Indien jy of jou kind hulle het, mag jy of jou kind dalk 'n ernstige reaksie op BIO TRANEXAMIC 500 gehad het. Jy of jou kind mag dalk dringende mediese aandag of hospitalisasie benodig.

**Vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:**

*Newe-effekte wat minder algemeen voorkom:*

- vorming van bloedklonte (ongewone pyn of swelling in jou arms of bene).

Hierdie is 'n ernstige newe-effek. Ju of jou kind mag dalk dringende mediese aandag benodig.

**Vertel jou dokter so gou as moontlik indien jy enige van die volgende opmerk:**

*Newe-effekte wat minder gereeld voorkom:*

- duiseligheid;
- probleme met jou visie, veral jou kleurvisie;
- naarheid (siek gevoel), braking (siek wees), diarree.

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, vertel asseblief jou dokter of apteker.

**Aanmelding van newe-effekte:**

Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegster.

Jy kan ook newe-effekte aan die Suid Afrikaanse Gesondheidsprodukte Regulatoriese Owerheid (SAHPRA) aanmeld deur die vorm te gebruik **6.04 Adverse Drug Reaction Reporting Form**, wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8.

Deur newe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van BIO TRANEXAMIC 500 te verskaf.

**5. Hoe om BIO TRANEXAMIC 500 te bewaar**

- Bewaar teen of benede 25 °C.
- Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
- BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum wat op die ettiket/ karton gedruk is nie.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

**6. Inhoud van die pak en ander inligting**
**Wat BIO TRANEXAMIC 500 bevat**

Die aktiewe bestanddeel is tranksamiensuur.
Elke filmbedekte tablet bevat 500 mg traneksamiensuur.

Die ander bestanddele is kolloïdale watervrye silika, kroskarmellose sellulose, makrogol 8 000, magnesiumstereaat (E572), metakrilaat polimere, mikrokristallyne sellulose (E460), povidoon (E1201), talk (E553b), titaandioksied (E171) en vanillien.

**Hoe BIO TRANEXAMIC 500 lyk en die inhoud van die pak**

Wit tot naaswit, filmbedekte, kapsuulvormige, bikonvekse, 18 mm lang en 8 mm wye tablette met 'n breeklyn en "TXA 500" op gedruk.

10 filmbedekte tablette word verpak in een PVC/ aluminium stulpstrook.

PVC/ aluminium stulpstroke word verpak in 'n buitenste kartonboks.

*Pakgroottes:*

30 of 100 filmbedekte tablette.

Nie alle pakgroottes mag bemark word nie.

**Houer van die Sertifikaat van Registrasie**

Biotech Laboratories (Edms) Bpk
Grondvloer, Blok K Wes, Central park
16de Weg 400, Randjespark
Midrand 1685
011 848 3050

**Hierdie pamflet is laas hersien**

Datum van registrasie: 29 Junie 2021
Datum van hersiening: 01 November 2022

**Registrasienommer**

42/8.1/0837