Clean Proposed Patient Information Leaflet for CYNEX 500 mg INJECTION

SCHEDULING STATUS

S4

CYNEX 500 mg INJECTION, solution for injection

Tranexamic acid

Sugar free

Read all of this leaflet carefully before you are given CYNEX 500 mg INJECTION.

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

What is in this leaflet:

1. What CYNEX 500 mg INJECTION is and what it is used for
2. What you need to know before CYNEX 500 mg INJECTION is administered
3. How CYNEX 500 mg INJECTION is administered
4. Possible side effects
5. How to store CYNEX 500 mg INJECTION
6. Contents of the pack and other information.

1. What CYNEX 500 mg INJECTION is and what it is used for

CYNEX 500 mg INJECTION contains tranexamic acid which forms part of a group of medicines called antihemorrhagics; antifibrinolytics, amino acids, which is used for the prevention and treatment of bleeding due to a process that inhibits blood clotting called fibrinolysis.

CYNEX 500 mg INJECTION is used to reduce bleeding for a short period of time. You may have been prescribed it for one of the following:

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- Prostate.
- Bladder surgery.

2. What you need to know before CYNEX 500 mg INJECTION is administered

CYNEX 500 mg INJECTION should not be administered to you:

- If you are hypersensitive (allergic) to tranexamic acid or any of the other ingredients of CYNEX 500 mg INJECTION (listed in section 6).
- If you have abnormal colour vision.
- If you experience massive upper urinary tract bleeding.
- If you have a tendency or a history of developing blood clots.
- If you have a condition in which a blood clot in a vein causes pain and inflammation (thrombophlebitis).
- If you have a condition affecting the ability of your blood to clot and thereby stop bleeding.
- If you suffer from a liver disorder.
- If you suffer from an abnormal and very dangerous condition in which blood collects beneath a membrane that covers the brain.
- If you are pregnant or breastfeeding (see section 2, “Pregnancy and breastfeeding”).

Warnings and precautions:

Tell your doctor or health care provider before being administered the injection:

- If you have a kidney disorder, you should receive lower doses.
- If you do not know why you suffer from menorrhagia (heavy menstrual bleeding or bleeding that lasts longer than 7 days), the cause for menorrhagia should first be established.
- If you have had seizures (convulsions or fits).
- If you are receiving CYNEX 500 mg INJECTION for a long period of time (you should undergo regular eye examinations).
- If you have blood in your urine, it may lead to urinary tract obstruction.
- If you have ever had any uncontrollable bleeding.
- If you suffer from excessive clotting or bleeding throughout your body (disseminated intravascular coagulation). Your doctor may carry out a blood test to see if the process that inhibits blood clotting (called

fibrinolysis) is activated.

- If you are at risk of having blood clots.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Children and adolescents

Do not give CYNEX 500 mg Injection to children because data on efficacy and safety is limited.

Other medicines and CYNEX 500 mg INJECTION:

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

The following medicines may interact with CYNEX 500 mg INJECTION:

- Medicines that help blood to clot, such as antifibrinolytic medicines.
- Thrombolytic medicines (medicines that prevent blood clotting) may oppose the action of CYNEX 500 mg INJECTION.
- Certain hormones (oestrogens) may increase the potential for developing blood clots.

Pregnancy and breastfeeding:

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 CYNEX 500 mg INJECTION. You should not receive CYNEX 500 mg INJECTION if you are pregnant or breastfeeding.

Driving and using machines:

It is not always possible to predict to what extent CYNEX 500 mg INJECTION may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CYNEX 500 mg INJECTION affects them.

CYNEX 500 mg INJECTION contains sodium:

This medicine contains less than 1 mmol sodium (23 mg) per unit volume, that is to say it is essentially sodium free.

3. How CYNEX 500 mg INJECTION will be administered

You will not be expected to give yourself CYNEX 500 mg INJECTION. It will be given to you by a person who

is qualified to do so, as a slow intravenous infusion/injection over a period of at least five minutes.

Administration by injection is usually changed to oral administration after a few days.

Your doctor will decide the correct dose to obtain the results needed. The dose of CYNEX 500 mg INJECTION will be different in each patient depending on your condition and body weight.

Your doctor will tell you how long the treatment will last.

The dose will be reduced if you have kidney disease.

If you have the impression that the effect of CYNEX 500 mg INJECTION is too strong or too weak, tell your doctor or pharmacist.

If you receive more CYNEX 500 mg INJECTION than you should:

Since a health care provider will administer CYNEX 500 mg INJECTION, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you forget to receive CYNEX 500 mg INJECTION:

Since a health care provider will administer CYNEX 500 mg INJECTION, it is unlikely that the dose will be missed.

4. Possible side effects

CYNEX 500 mg INJECTION may have side effects.

Not all side effects reported for CYNEX 500 mg INJECTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CYNEX 500 mg INJECTION, please consult your health care provider for advice.

If any of the following happens, stop receiving CYNEX 500 mg INJECTION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips and 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 allergic reaction to CYNEX 500 mg 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:

- Blood clotting complications (such as swelling, redness, warmth and pain in arms and legs).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Eye disturbances (such as colour disturbances or blurred vision).
- Nausea (feeling sick), vomiting (being sick), diarrhoea.

Less frequent side effects:

- Low blood pressure manifested as light-headedness, dizziness, or even fainting.

Frequency unknown:

- Seizures (convulsions or fits).

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CYNEX 500 mg INJECTION.

5. How to store CYNEX 500 mg INJECTION

Store at or below 30 °C.

Protect from light. Do not refrigerate.

Keep the ampoules in the outer carton until required for use.

For single use only. Discard any unused portion.

Do not use CYNEX 500 mg INJECTION after the expiry date on the carton.

Return all unused medicine to the pharmacy for disposal.

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

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

6. Contents of the pack and other information

What CYNEX 500 mg INJECTION contains:

The active substance is tranexamic acid.

Each 5 mL ampoule contains 500 mg tranexamic acid.

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The other ingredients are hydrochloric acid, sodium hydroxide and water for injection.

What CYNEX 500 mg INJECTION looks like and contents of the pack:

Clear, colourless liquid, free from visible particles.

Contents of the pack:

5 mL clear, colourless USP type-I OPC glass ampoule with a blue dot and three brown bands.

Pack size:

Five ampoules are packed into a plastic tray, which is packed in an outer carton.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1, Roodepoort

Johannesburg 1724

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Namibia	NS2 23/8.1/0009
Botswana	S2 A2000097

Signed: Mpho Seima

Pasiëntinligtingsblad vir CYNEX 500 mg INJECTION

SKEDULERINGSTATUS: S4

CYNEX 500 mg INJECTION, oplossing vir inspuiting

Traneksaamsuur

Suikervry

Lees hierdie inligtingsblad noukeurig deur voordat CYNEX 500 mg INJECTION vir jou gegee word.

- Hou hierdie inligtingsblad. Dit mag nodig wees om dit later weer te lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad:

1. Wat is CYNEX 500 mg INJECTION en waarvoor word dit gebruik
2. Wat jy moet weet voordat CYNEX 500 mg INJECTION toegedien word
3. Hoe CYNEX 500 mg INJECTION toegedien gaan word
4. Moontlike newe-effekte
5. Hoe om CYNEX 500 mg INJECTION te berg
6. Inhoud van die verpakking en ander inligting.

1. Wat is CYNEX 500 mg INJECTION en waarvoor word dit gebruik

CYNEX 500 mg INJECTION bevat traneksaamsuur wat deel vorm van ’n groep medisynes genaamd antihemorragiese middels; antifibrinolitika, aminosure, wat gebruik word vir die voorkoming en behandeling van bloeding weens ’n proses wat bloedstolling onderdruk, bekend as fibrinolise.

CYNEX 500 mg INJECTION word gebruik om bloeding vir ’n kort tydperk te verminder. Dit kon vir een van die volgende vir jou voorgeskryf gewees het:

- Chirurgie van die prostaat.
- Chirurgie van die blaas.

2. Wat jy moet weet voordat CYNEX 500 mg INJECTION toegedien word

CYNEX 500 mg INJECTION moenie aan jou toegedien word nie:

- Indien jy hipersensitief (allergies) vir traneksaamsuur of vir enige van die ander bestanddele van CYNEX 500 mg INJECTION is (gelys by afdeling 6).
- Indien jy abnormale kleurvisie het.
- Indien jy massiewe bloeding in die boonste urienweg ondervind.
- Indien jy ’n geneigdheid het vir of ’n geskiedenis van ontwikkeling van bloedklonte het.
- Indien jy ’n toestand het waar ’n bloedklont in ’n aar pyn en inflammasie veroorsaak (tromboflebitis).
- Indien jy ’n toestand het wat die vermoë affekteer van jou bloed om te stol en sodoende bloeding te laat ophou.
- Indien jy aan ’n lewerversteuring ly.
- Indien jy aan ’n abnormale en baie gevaarlike toestand ly, waar die bloed versamel onder ’n membraan wat die brein bedek.
- Indien jy swanger is of jou baba borsvoed (sien afdeling 2, “Swangerskap en borsvoeding”).

Waarskuwings en voorsorgmaatreëls:

Sê vir jou dokter of gesondheidsorgverskaffer voordat die inspuiting aan jou toegedien word:

- Indien jy ’n niersversteuring het, jy behoort dan laer dosisse te ontvang.
- Indien jy nie weet waarom jy aan menorragie (swaar menstruele bloeding of bloeding wat vir langer as 7 dae aanhou) ly nie, moet die oorsaak van die menorragie eers bepaal word.

- Indien jy toevalle kry (konvulsies of stuipe).
- Indien jy CYNEX 500 mg INJECTION vir ’n lang tydperk ontvang (jy behoort gereeld oogondersoeke te ondergaan).
- Indien jy bloed in jou urine het, kan dit tot urienwegobstruksie lei.
- Indien jy al ooit enige onstuitbare bloeding gehad het.
- Indien jy aan oormatige stolling of bloeding dwarsdeur jou liggaam ly (gedissemineerde intravaskulêre koagulasie). Jou dokter kan ’n bloedtoets uitvoer om te sien of die proses wat bloedstolling onderdruk (genaamd fibrinolise) geaktiveer is.
- Indien jy ’n risiko het om bloedklonte te kry.

Konsulteer asseblief jou dokter, selfs al was hierdie stellings iewers in die verlede op jou van toepassing.

Kinders en adolessente

Moet nie CYNEX 500 mg Inspuiting aan kinders gee nie, aangesien daar beperkte data oor doeltreffendheid en veiligheid is.

Ander medisynes en CYNEX 500 mg INJECTION:

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisynes in.)

Die volgende medisynes kan wisselwerking met CYNEX 500 mg INJECTION hê:

- Medisynes wat help dat bloed stol, soos antifibrinolitiese medisynes.
- Trombolitiese medisynes (medisynes wat bloedstolling voorkom) kan die aksie van CYNEX 500 mg INJECTION teenwerk.
- Sekere hormone (estrogene) kan die potensiaal verhoog om bloedklonte te ontwikkel.

Swangerskap en borsvoeding:

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of gesondheidsorgverskaffer voordat jy CYNEX 500 mg INJECTION ontvang.

Jy moenie CYNEX 500 mg INJECTION ontvang indien jy swanger is of borsvoed nie.

Bestuur en gebruik van masjiene:

Dit is nie altyd moontlik om te voorspel tot watter mate CYNEX 500 mg INJECTION met die daaglikse aktiwiteite van ’n pasiënt mag inmeng nie. Pasiënte moet seker maak dat hulle nie bogenoemde aktiwiteite uitvoer nie, totdat hulle weet tot watter mate CYNEX 500 mg INJECTION hulle affekteer.

CYNEX 500 mg INJECTION bevat natrium:

Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per eenheidsvolume, dit is dus wesenlik natriumvry.

3. Hoe CYNEX 500 mg INJECTION toegedien gaan word

Daar sal nie van jou verwag word om CYNEX 500 mg INJECTION self toe te dien nie. Dit sal vir jou gegee word deur ’n persoon wat gekwalifiseerd is daarvoor, as ’n stadige intraveneuse infusie/inspuiting oor ’n tydperk van ten minste vyf minute. Toediening via inspuiting word gewoonlik na ’n paar dae verander na mondelikse toediening.

Jou dokter gaan besluit wat die regte dosis is om die vereiste resultate te verkry. Die dosis van CYNEX 500 mg INJECTION sal vir elke pasiënt verskil, afhangende van jou toestand en liggaamsgewig.

Jou dokter sal jou inlig hoe lank die behandeling gaan duur.

Die dosis sal verlaag word indien jy niersiekte het.

Indien jy die indruk kry dat die uitwerking van CYNEX 500 mg INJECTION te sterk of te swak is, bespreek dit met jou dokter of apteker.

Indien jy meer CYNEX 500 mg INJECTION ontvang as wat jy moet:

Aangesien ’n gesondheidsorgverskaffer CYNEX 500 mg INJECTION gaan toedien, sal hy/sy die dosis kontroleer. In geval oordosering wel voorkom, sal jou dokter dit hanteer.

Indien jy vergeet om CYNEX 500 mg INJECTION te ontvang:

Aangesien ’n gesondheidsorgverskaffer CYNEX 500 mg INJECTION gaan toedien, is dit onwaarskynlik dat ’n dosis oorgeslaan sal word.

4. Moontlike newe-effekte

CYNEX 500 mg INJECTION kan newe-effekte hê.

Nie alle newe-effekte wat vir CYNEX 500 mg INJECTION gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou verswak of indien jy enige ongunstige effekte ondervind terwyl jy CYNEX 500 mg INJECTION ontvang, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg.

Indien enige van die volgende voorkom, hou op om CYNEX 500 mg INJECTION te ontvang en sê onmiddellik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk en asemhaling kan veroorsaak.
- Uitslag of gejeuk
- Floute.

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy ’n ernstige allergiese reaksie op CYNEX 500 mg INJECTION gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Indien jy enige van die volgende newe-effekte opmerk, sê onmiddellik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal:

- Bloedstollingskomplikasies (soos swelling, rooiheid, warm gevoel en pyn in arms en bene).

Hierdie is ’n ernstige newe-effek. Jy mag dringend mediese sorg benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- Oogversteurings (soos versteurings van kleurwaarneming of dowwe visie).
- Naarheid (voel mislik), braking (gooi op), diarree.

Newe-effekte wat minder dikwels voorkom:

- Lae bloeddruk wat manifesteer as lighoofdigheid, duiseligheid of selfs floute.

Newe-effekte waarvan die frekwensie onbekend is:

- Toevalle (konvulsies of stuipe).

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

Rapportering van newe-effekte:

Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en e-verslaggewing platform (who-umc.org) gevind op SAHPRA webwerf.
Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die veiligheid van CYNEX 500 mg INJECTION te verskaf.

5. Hoe om CYNEX 500 mg INJECTION te berg

Bêre by of onder 30 °C.

Beskerm teen lig. Moenie in die yskas berg nie.

Hou die ampulle in die buitenste karton tot nodig vir gebruik.

Slegs vir enkelgebruik. Doen enige ongebruikte oplossing weg.

Moenie CYNEX 500 mg INJECTION gebruik ná die vervaldatum wat op die karton voorkom nie.

Neem alle ongebruikte medisyne terug na die apteek vir wegdoening.

Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) wegdoen nie.

HOU BUITE BEREIK EN SIG VAN KINDERS.

6. Inhoud van die verpakking en ander inligting

Wat CYNEX 500 mg INJECTION bevat:

Die aktiewe bestanddeel is traneksaamsuur.

Elke 5 mL ampul bevat 500 mg traneksaamsuur.

Die ander bestanddele is soutsuur, natriumhidroksied en water vir inspuiting.

Hoe CYNEX 500 mg INJECTION lyk en inhoud van die verpakking:

Deurskynende, kleurlose vloeistof, sonder enige sigbare deeltjies.

Inhoud van die verpakking:

5 mL deurskynende, kleurlose USP tipe-I OPC-glasampul met ’n blou kol en drie bruin ringe.

Verpakkingsgrootte:

Vyf ampulle in ’n plat plastiekbakkie, verpak in ’n buitenste karton.

Houer van registrasiesertifikaat:

Ranbaxy Pharmaceuticals (Edms.) Bpk.

Lautreweg 14

Stormill Uitbr.1, Roodepoort

Johannesburg 1724

Hierdie inligtingsblad is laas hersien:

28 Oktober 2024

Registrasienommer:

43/8.1/0263

Datum van registrasie:

11 Junie 2018

Botswana	S2	BOT2103769

Namibia	NS2	23/8.1/0009