Jayshree Rughoonandan
Digitally signed by Jayshree Rughoonandan
Date: 2021.10.26 11:05:22 +02'00'

Harsha Gopal Jivan
Digitally signed by Harsha Gopal Jivan
Date: 2021.10.26 13:10:13 +02'00'

SCHEDULING STATUS S4

PROPRIETARY NAME AND DOSAGE FORM

Fibreaker 1 500 000 IU Injection

COMPOSITION
Streptokinase 1 500 000 IU per vial.

Other ingredients are: Human albumin and polygeline (gelofusine).

PHARMACOLOGICAL CLASSIFICATION
A 31 Enzymatic preparations.

PHARMACOLOGICAL ACTION
Pharmacodynamic properties:
Streptokinase is a highly purified protein derived from the culture filtrate of β-haemolytic streptococci. It has no intrinsic enzymatic activity, but it combines with human plasminogen to form a plasminogen activator complex that converts plasminogen to the proteolytic enzyme, plasmin. Plasmin is a relatively non-specific protease. It digests fibrin clots as well as fibrinogen and other plasma proteins. Intravenous infusion of streptokinase is followed by increased fibrinolytic activity, which decreases plasma fibrinogen levels. The decrease in plasma fibrinogen is associated with decreases in plasma and blood viscosity and red blood cell aggregation.

Pharmacokinetic properties:
Streptokinase is rapidly cleared from the circulation after intravenous infusion. Following rapid, high-dose administration, the half-life is about 23 minutes (as active activator complex activity). Elevation of the anti-streptokinase antibody titre usually occurs about 5 to 7 days following administration, reaches a peak after 2 to 3 weeks, and may persist for 1 year or longer.

INDICATIONS
Acute myocardial infarction in adults.

CONTRAINDICATIONS
FIBREAKER 1 500 000 IU must not be used in the case of severe allergic reactions to streptokinase or other ingredients of FIBREAKER 1 500 000 IU. Because of the increased risk of haemorrhage under thrombolytic therapy, FIBREAKER 1 500 000 IU is contraindicated in the following situations:
- existing or recent internal bleeding
- a recent history of peptic ulcer disease
- oesophageal varices
- ulcerative colitis
- other bleeding gastrointestinal lesions
- all forms of reduced blood coagulability, in particular spontaneous fibrinolysis and uncontrollable clotting disorders
- recent cerebrovascular accident, intracranial or intraspinal surgery
- intracranial neoplasm
- recent head trauma
- known neoplasm with risk of haemorrhage
- acute pancreatitis
- severe uncontrollable hypertension with systolic values above 200 mmHg and/or diastolic values above 100 mmHg or hypertensive retinal changes Grades III/IV
- local lesions with risk of bleeding (e.g. gastrointestinal conditions with existing haemorrhage, previous translumbar aortography, puncture of large arteries, intramuscular injections, in-dwelling catheters or endotracheal tubes)
- recent operations up to the 6th to 10th postoperative day, depending on the extent of the procedure
- recent trauma
- recent organ biopsy, puncture of non-compressible vessels, intramuscular injections or intubation
- recent delivery or abortion
- diseases of the urogenital tract with existing or potential sources of bleeding (e.g. in-dwelling bladder catheter)
- septic thrombotic disease
- suspicion of atherosclerotic vessel degeneration, cerebrovascular diseases, severe diabetes mellitus, diabetic/haemorrhagic retinopathy
- severe liver or kidney damages
- mitral valve defects or atrial fibrillation
- endocarditis
- pericarditis: isolated cases of a pericarditis, misdiagnosed as acute myocardial infarction and treated with FIBREAKER 1 500 000 IU, have resulted in pericardial effusions including tamponade
- previous translumbar aortography
- disorders of cerebral blood flow or recent cerebral haemorrhage

FIBREAKER 1 500 000 IU should not be given in pregnancy, particularly in the first 18 weeks because of the risk of placental separation. Because of the increased likelihood of resistance due to anti-streptokinase antibodies, further doses of FIBREAKER 1 500 000 IU should not be given in the period between 5 days and 12 months after the initial dose.

Local administration:
A systemic effect is also possible, after local administration, depending on the volume of the dose administered. Therefore, the contraindications mentioned above should also be considered for the local administration.

WARNINGS AND SPECIAL PRECAUTIONS
Bleeding:
FIBREAKER 1 500 000 IU may cause haemorrhage, particularly from needle puncture sites. A small bore needle should be used and the number of punctures should be limited. Upper extremity vessels are preferable in the event where an arterial puncture is necessary during intravenous therapy. After the puncture, pressure should be applied for at least 30 minutes. A pressure dressing should be applied and the puncture site checked frequently for evidence of bleeding.

Patients with mitral valve defects associated with atrial fibrillation are more likely to have left heart thrombus which may lead to cerebral embolism following thrombolytic therapy. There is a risk of retinal bleeding in patients with diabetic retinopathy.

FIBREAKER 1 500 000 IU is unlikely to be effective in the following conditions:
- deep vein thrombosis more than 14 days old
- occlusion of central retinal artery more than 6 to 8 hours old and thrombosis of retinal vein more than 10 days old

The effect may also be reduced in patients with recent streptococcal infections such as streptococcal pharyngitis, acute rheumatic fever and acute glomerulonephritis.

Special precautions:
FIBREAKER 1 500 000 IU should be used with great care, if at all, in patients with increased risk of bleeding, or those in whom haemorrhage is likely to prove particularly dangerous. In serious haemorrhagic complications, FIBREAKER 1 500 000 IU therapy should be discontinued and a proteinase inhibitor e.g. aprotinin should be given in the following dosage:
Initially inject 500 000 KIU to 1 000 000 KIU (Kallikrein Inactivator Unit) by slow intravenous injection or infusion (maximum rate 5 ml/min).
If necessary, this should be followed by 200 000 KIU 4 hourly until the bleeding stops.
In addition, combination with synthetic antifibrinolytics is recommended. If necessary, clotting factors can be substituted.
If acute or recurrent pulmonary embolism occurs during the treatment, the course of FIBREAKER 1 500 000 IU should be continued as originally planned so as to lyse the emboli. There is an increased risk of haemorrhage in patients who are receiving or who have recently been treated with anticoagulants or substances which act on platelet formation or function.

Before starting long-term systemic lysis with FIBREAKER 1 500 000 IU, the effects of medicines which act upon platelet formation or function should be allowed to subside. If the patient has previously been receiving heparin, it should be neutralised by the administration of protamine sulphate before the start of the thrombolytic therapy. The FIBREAKER 1 500 000 IU infusion can then be started after 4 hours. Before starting FIBREAKER 1 500 000 IU therapy, the thrombin time should not be more than twice the normal control value before thrombolytic therapy is started. In patients previously treated with warfarin, the INR (International Normalised Ratio) must be less then 1,7 (approximate prothrombin index at least 50 %) before starting FIBREAKER 1 500 000 IU infusion.
Care should be taken when physically handling patients. FIBREAKER 1 500 000 IU should be used with care in elderly patients.
Anti-streptokinase antibodies are formed after FIBREAKER 1 500 000 IU use, with antibody titres rising abruptly after about 5 to 10 days and returning to normal only after up to 6 months. These antibodies may cause resistance or hypersensitivity to subsequent doses of FIBREAKER 1 500 000 IU. Therefore, further doses of FIBREAKER 1 500 000 IU should not be given in the period between 5 days and 12 months after the initial dose (even longer periods have been suggested). If thrombolytic therapy is required in this period, an alternative non-antigenic medicine should be used. On termination of FIBREAKER 1 500 000 IU treatment, the patient should be given anticoagulants in an attempt to prevent re-thrombosis. Preferably heparin should be given, starting 4 hours after the end of thrombolysis and then an oral anticoagulant may be introduced after 14 hours of FIBREAKER 1 500 000 IU discontinuation.
High titres of anti-streptokinase antibodies may also occur in patients after some streptococcal infections such as streptococcal pharyngitis or acute rheumatic fever or in those with acute glomerulonephritis secondary to streptococcal infections. In such patients there may be resistance to streptokinase or a reduced effect. It is recommended that intramuscular injection be avoided for the first 24 hours.

Allergic reactions to FIBREAKER 1 500 000 IU can be largely avoided by giving the initial intravenous dose slowly. Corticosteroids can also be given prophylactically (e.g. 100 to 250 mg methylprednisolone 10 minutes before starting FIBREAKER 1 500 000 IU therapy). If an allergic reaction occurs the infusion should be discontinued and the patient given intravenous corticosteroids together with epinephrine (adrenaline) and an antihistamine. Once the symptoms have subsided, treatment can be continued. If an anaphylactic reaction occurs, discontinue the infusion immediately and give epinephrine (adrenaline) immediately by slow intravenous injection. In addition, high doses of corticosteroids by slow intravenous injection may be given.

Effects on ability to drive and use machinery:
FIBREAKER 1 500 000 IU will not have an effect on the ability to drive or use machinery as it is administered in hospital.

INTERACTIONS
There is an increased risk of haemorrhage in patients who are receiving or who have recently been treated with anticoagulants or substances which act upon the platelet formation or function (e.g. platelet aggregation inhibitors, acetylsalicylic acid, allopurinol, anabolic steroids, androgens, thyroid hormones, volatile oils, quinidine, chlofibric acid derivatives, phenylbutazone, indomethacin, aryl acetic acid and aryl propionic acid derivatives, tetracyclines, valproic acid, thiouracils, sulphonamides and dextran). Before starting long-term systemic lysis with FIBREAKER 1 500 000 IU, the effects of medicines which act upon platelet formation or function, should be allowed to subside. If the patient has previously been receiving heparin it should be neutralised by the administration of protamine sulphate before the start of the thrombolytic therapy. See WARNINGS AND SPECIAL PRECAUTIONS before proceeding with therapy.

PREGNANCY AND LACTATION
Pregnancy:
FIBREAKER 1 500 000 IU should not be given during the first 18 weeks of pregnancy or during heavy vaginal bleeding or after recent delivery or abortion unless absolutely necessary. (See CONTRAINDICATIONS).

Lactation:
The safety in lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE
Method for reconstitution:
Sodium chloride 0,9 % (physiological saline) is the preferred diluent for FIBREAKER 1 500 000 IU although dextrose 5 % in water may be used.

1. Add 5 ml of the diluent slowly to the vial of FIBREAKER 1 500 000 IU, directing the needle point to the wall of the vial rather than into the medicine powder. Abolish residual vacuum by briefly loosening the needle from the syringe.
2. Tilt and roll vial gently. Swirl the contents gently to affect dissolution. DO NOT SHAKE TO AVOID FOAMING.
3. Once the powder is completely dissolved, transfer the content of the vial into 45 to 100 ml of the physiological saline.
4. DO NOT ADD ANY OTHER MEDICATION TO FIBREAKER 1 500 000 IU VIALS.
5. Because FIBREAKER 1 500 000 IU does not contain preservatives, it should be reconstituted immediately before use.

An intradermal skin test of 100 IU has been suggested to predict allergic response to FIBREAKER 1 500 000 IU. If a positive reaction is not seen after 15 to 20 minutes, the therapeutic dose can be administered.

Administration:
For short-term lysis in the treatment of an acute myocardial infarction:
FIBREAKER 1 500 000 IU is administered by intravenous, intra-arterial or intracoronary infusion as soon as possible within the first 6 hours after onset of infarction.
Acute evolving transmural myocardial infarction:
1. Intravenous infusion: 1 500 000 IU: FIBREAKER 1 500 000 IU is made up in 100 ml of physiological saline or dextrose solution and administered over 30 to 60 minutes.
2. Paediatric Use: Sufficient experience with FIBREAKER 1 500 000 IU therapy in children is not available.

If hypotension occurs, it can usually be controlled by temporarily slowing the infusion rate.

SIDE EFFECTS
Blood and lymphatic disorders:
Frequent: Haemorrhages, including gastrointestinal and liver haemorrhages, splenic rupture, urogenital haemorrhages.
Less frequent: Intracranial haemorrhage with their complications (which may be fatal) or retroperitoneal haemorrhage. During thrombolytic treatment of acute myocardial infarction, haemorrhage into the pericardium, including myocardial rupture may occur. Haemorrhage may occur in any tissue and organ in the body and can present with symptoms affecting any body system, including the abdomen, cardiovascular, joints and CNS. Haemorrhage should be considered as a potential cause of unusual symptoms occurring after administration.

Cardiac disorders:
Less frequent: Cardiac dysrhythmias, myocardial infarction, persistent angina pectoris and cardiac failure, possibly leading to cardiac and respiratory arrest. Cardiovascular hypoxia, bradycardia.

Eye disorders:
Less frequent: Uveitis and retinal artery occlusion, iritis, retinal haemorrhages.

Hepato-biliary disorders:
Frequent: Transient increases in liver function tests or bilirubin. Jaundice, liver haematoma.
Less frequent: Respiratory, thoracic and mediastinal disorders. Fatal acute respiratory distress syndrome (due to allergic reactions).

Vascular disorders:
Frequent: Hypotension. If hypotension occurs, it can usually be controlled by temporarily slowing the infusion rate.
Less frequent: Acute or recurrent pulmonary embolism. The break-up of existing clots may occasionally produce emboli elsewhere. Vasculitis. Non-cardiogenic, pulmonary oedema. Cholesterol embolism. Haemorrhagic or thromboembolic stroke. Gangrenous digits. Hypertension.

Gastrointestinal disorders:
Less frequent: Gastrointestinal bleeding, retroperitoneal bleeding, splenic rupture. Bowel infarction. Nausea and vomiting, abdominal pain.

Endocrine disorders:
Less frequent: Pancreatitis.

General disorders and administration site conditions:
Frequent: Haemorrhage from puncture sites. Fever and chills. Lower back and abdominal pain. Headache, asthenia and malaise.

Immune system disorders:
Frequent: Development of anti-streptokinase antibodies. Allergic reactions e.g. skin rash, flushing or redness of skin, dyspnoea, oedema, bronchospasm, less frequent anaphylactoid and serum sickness-like symptoms, hives or itching, troubled breathing or wheezing.
Less frequent: "Purple toe" syndrome.

Skin and subcutaneous tissue disorders:
Less frequent: Livedo reticularis (purplish red, net-like, blotchy spots on skin). Skin rashes, hives.

Musculoskeletal and connective tissue disorders:
Frequent: Musculoskeletal pain, such as back pain.
Less frequent: Arthritis. Rhabdomyolysis.

Nervous system disorders:
Less frequent: Neuro-allergic symptoms (Guillain-Barré syndrome, polyneuropathy). Cerebral convulsions. Cerebral or spinal cord infarction. Headache. Cerebral haemorrhage.

Renal and urinary disorders:
Less frequent: Nephritis. Acute renal failure.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
In the event of accidental overdosage, treatment is symptomatic and supportive.

IDENTIFICATION
A white powder or a white friable solid/cake in a 12 ml clear glass vial sealed with a grey bromobutyl rubber bung and closed with a lime-green coloured aluminium flip-off seal.

PRESENTATION
A white powder or a white friable solid, hygroscopic cake packed in a 12 ml standardised 8R injection glass vial sealed with a grey bromobutyl rubber bung and closed with a lime-green coloured aluminium flip-off seal. Vials are individually packed in cartons.

STORAGE INSTRUCTIONS
Store between 2 and 8 °C. Do not freeze. Protect from light.
The dry substance must not be used after the expiry date printed on the pack and container.
The solution must be used immediately after reconstitution.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
44/31/0010

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Gen-Eye (Pty) Ltd[1]
Unit 7, Royal Palm Business Estate
646 Washington Street, Halfway House
Midrand, 1685
Gauteng, South Africa
[1] Company Registration number: 2009/009360/07

DATE OF PUBLICATION OF THE PACKAGE INSERT
Date of registration: 23 November 2017
Date of the most recently revised package insert as approved by SAHPRA: 19 October 2021

FIB/PI/03/09.2021

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FIBREAKER 1 500 000 IU Injection

Streptokinase 1 500 000 IU

Read all of this leaflet carefully before FIBREAKER 1 500 000 IU is administered to you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- FIBREAKER 1 500 000 IU 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 as yours.

1. WHAT FIBREAKER 1 500 000 IU CONTAINS
The active substance is streptokinase 1 500 000 IU per vial.
The other ingredients are human albumin and polygeline.

2. WHAT FIBREAKER 1 500 000 IU IS USED FOR
FIBREAKER 1 500 000 IU is a highly purified protein that digests fibrin clots and other plasma proteins.
It is used in adults in the following condition:
- When a clot has formed in the heart muscle interrupting the blood supply to the area.

3. BEFORE RECEIVING FIBREAKER 1 500 000 IU
Do not receive FIBREAKER 1 500 000 IU:
- if you have severe allergic reactions to streptokinase or any of the other ingredients of FIBREAKER 1 500 000 IU
- if you have or recently had any internal bleeding from ulcers or lesions
- if your blood tends to form clots
- if you have inflammation of the pancreas
- if you have had recent surgery (within the last 10 days)
- if you suffer from high blood pressure (uncontrolled) or if you bleed easily
- if you had a recent stroke
- if you have oesophageal varices (enlarged veins of the lower oesophagus)
- if you have a brain tumour
- if you recently had head trauma or other trauma
- if you recently had an organ biopsy, puncture of non-compressible vessels, intramuscular injections or intubation
- if you recently had a delivery or abortion
- if you have any disease of the urogenital tract (reproductive organs and the urinary system) with existing or potential sources of bleeding
- if you suspect you may have atherosclerosis (build up of deposits in the arteries), any condition that affects the circulation of blood to the brain, severe diabetes, damage to the retina of the eye
- if you have lung diseases with cavitation (e.g. open tuberculosis) or severe bronchitis
- if you have liver or kidney damage
- if you have any heart valve defects or any heart rhythm disorders
- if you have endocarditis (inflammation of the inner layer of the heart)
- if you have pericarditis (inflammation of the fibrous sac surrounding the heart)
- if you have previously had a translumber aortography (injection of contrast material while taking x-rays of the aorta)
- if you are within the first 18 weeks of pregnancy

FIBREAKER 1 500 000 IU injection should not be given to children.

Local administration:
Your doctor will consider the above contraindications for local administration as a systemic effect is also possible after local administration.

Take special care with FIBREAKER 1 500 000 IU:
- if there is an increased risk of bleeding or if it will be very dangerous for you to bleed
- if you are taking or have recently taken medication to prevent clotting of your blood
- if you have any heart valve defects related to heart rhythm disorders
- if you have retinal damage caused by diabetes
- if you are elderly

Pregnancy and breastfeeding:
You should not have a FIBREAKER 1 500 000 IU injection during the first 18 weeks of pregnancy or during heavy vaginal bleeding or just after delivery or abortion or if you are breastfeeding your baby.

Driving and using machinery:
FIBREAKER 1 500 000 IU will not have an effect on your ability to drive or use machinery as it will be administered to you in hospital.

Taking/Using other medicines with FIBREAKER 1 500 000 IU:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicine) If you are receiving or have recently been treated with anti-blood clotting medicines or substances which act upon the platelet formation or function, please consult with your doctor as you may have an increased risk of bleeding. Examples of such medicine are: platelet aggregation inhibitors, acetylsalicylic acid, allopurinol, anabolic steroids, androgens, thyroid hormones, volatile oils, quinidine, chlofibric acid derivatives, indomethacin, aryl acetic acid and aryl propionic acid derivatives, tetracyclines, valproic acid, thiouracils, sulphonamides and dextran.

4. HOW TO RECEIVE FIBREAKER 1 500 000 IU
You will not be expected to give yourself FIBREAKER 1 500 000 IU. It will be given to you by a person who is qualified to do so.

If you receive more FIBREAKER 1 500 000 IU than you should:
Since a healthcare professional will administer FIBREAKER 1 500 000 IU, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

5. POSSIBLE SIDE EFFECTS
FIBREAKER 1 500 000 IU can have side effects. The most frequent side effects are bleeding from recent cuts, wounds, lesions or ulcers and bleeding from the injection site. Not all side effects reported for FIBREAKER 1 500 000 IU are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop receiving FIBREAKER 1 500 000 IU and tell your doctor immediately:
- Difficulty breathing.
- Skin rash.
- Flushing or redness of the skin.
- Hives or itching.
- Fluid retention in the body (swelling).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FIBREAKER 1 500 000 IU. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:
- Difficulty breathing.
- Heart attack or heart failure.
- Chest pain.
- Lack of oxygen to the heart.
- Inflammation of the eye (uveitis or iritis).
- Loss of vision (retinal artery occlusion).
- Bleeding of the eye (retinal haemorrhages).
- Increase in liver function or bilirubin.
- Yellowing of the skin and/or eyes (jaundice).
- Abdominal pain (liver haematoma).
- Blood clots elsewhere.
- Inflammation that destroys blood vessels (vasculitis).
- Fluid in the lungs (pulmonary oedema).
- Cholesterol that obstructs blood vessels (cholesterol embolism).
- Body tissue death of fingers/toes (gangrenous fingers/toes).
- Inflammation of the pancreas (pancreatitis).
- Fever and chills.
- Lower back pain.
- Development of antistreptokinase antibodies.
- Discolouration of the toes ("Purple toe" syndrome).
- Purplish red, net-like, blotchy spots on the skin (livedo reticularis).
- Breakdown of damaged skeletal muscle tissue (rhabdomyolysis).
- Seizures (cerebral convulsions).
- Tissue death of the brain or spinal cord (cerebral or spinal cord infarction).
- Bleeding of the brain (cerebral haemorrhage).
- Inflammation of the kidneys (nephritis).
- Kidney failure.

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

Tell your doctor if you notice any of the following:
- Fatigue, weakness, dizziness and fainting (bradycardia).
- Nausea and vomiting.
- Headache and general discomfort (malaise).
- Inflammation of the joints (arthritis).
- Weakness, numbness, pins-and-needles and burning pain (polyneuropathy).

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

6. STORING AND DISPOSING OF FIBREAKER 1 500 000 IU
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
FIBREAKER 1 500 000 IU is usually stored in the doctor's surgery or hospital.
It must be kept in a refrigerator, between 2 and 8 °C. Do not freeze. Protect from light.
Store in the original package.
Keep the vial in the outer carton.
The dry substance must not be used after the expiry date printed on the label and carton.
The solution must be used immediately after reconstitution.
The doctor who gives FIBREAKER 1 500 000 IU injection will generally dispose of the used vial in a Sharps container.

7. PRESENTATION OF FIBREAKER 1 500 000 IU
A white powder or a white friable solid, hygroscopic cake packed in a 12 ml standardised 8R injection glass vial sealed with a grey bromobutyl rubber bung and closed with a lime-green coloured aluminium flip off seal. Vials are individually packed in cartons.

8. IDENTIFICATION OF FIBREAKER 1 500 000 IU
A white powder or a white friable solid/cake in a 12 ml clear glass vial sealed with a grey bromobutyl rubber bung and closed with a lime-green coloured aluminium flip off seal.

9. REGISTRATION NUMBER/REFERENCE NUMBER
44/31/0010

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Gen-Eye (Pty) Ltd[1]
Unit 7, Royal Palm Business Estate
646 Washington Street, Halfway House
Midrand, 1685
Gauteng, South Africa
[1] Company Registration number: 2009/009360/07

11. DATE OF PUBLICATION
Date of registration: 23 November 2017
Date of the most recently revised patient information leaflet as approved by SAHPRA: 19 October 2021

FIB/PIL/03/09.2021

SKEDULERINGSTATUS S4

EIENDOMSNAAM EN DOSEERVORM

Fibreaker 1 500 000 IU Inspuiting

SAMESTELLING
Streptokinase 1 500 000 IE per flessie.

Ander bestanddele: Menslike albumien en poligelien (gelofusien).

FARMAKOLOGIESE KLASSIFIKASIE
A 31 Ensiempreparate.

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe:
Streptokinase is 'n hoogs gesuiwerde proteïen afkomstig van die kultuurfiltraat van β-hemolitiese streptokokke. Dit het geen intrinsieke ensiemaktiwiteit nie, maar dit kombineer met menslike plasminogeen om 'n plasminogeenaktiveerderkompleks te vorm wat plasminogeen na die proteolitiese ensiem plasmien omskakel. Plasmien is 'n relatief nonspesifieke protease. Dit verteer fibrienklonte asook fibrinogeen en ander plasmaproteïene. Binne-aarse toediening van streptokinase gee hoë fibrinolitiese aktiwiteit wat die vlakke van fibrinogeen in die plasma laat daal. Die daling in die hoeveelheid fibrinogeen in die plasma verander die viskositeit van plasma en bloed en die saamklonting van rooibloedselle.

Farmakokinetiese eienskappe:
Streptokinase word na binneaarse infusie vinnig uit die sirkulasie opgeruim. Na vinnige toediening van 'n hoë dosis is die halfleeftyd ongeveer 23 minute (as aktiewe aktiveerderkompleks). Styging in die titer van die anti-streptokinase antiliggame kom gewoonlik ongeveer 5 tot 7 dae na toediening voor, bereik 'n hoogtepunt na 2 tot 3 weke, en kan vir 1 jaar of langer voortduur.

INDIKASIES
Akute miokardiale infarksie in volwassenes.

KONTRAINDIKASIES
FIBREAKER 1 500 000 IU moet nie in die geval van ernstige allergiese reaksies teenoor streptokinase of ander bestanddele van FIBREAKER 1 500 000 IU gebruik word nie. As gevolg van die hoër risiko vir bloeding tydens trombolitiese behandeling is FIBREAKER 1 500 000 IU teenaangedui vir die volgende situasies:
- bestaande of onlangse interne bloeding
- 'n geskiedenis van onlangse maagsere
- esofageale spatare
- ulseratiewe kolitis
- ander bloeiende gastrointestinale letsels
- alle vorme van swak bloedstollingsvermoë, veral met spontane fibrinolise en onbeheerbare stollende toestande
- onlangse serebrovaskulêre ongeluk, intrakraniale of intraspinale chirurgie
- intrakraniale neoplasma
- onlangse trauma aan die kop
- bekende neoplasma met die risiko vir bloeding
- akute pankreatitis
- ernstige onbeheerbare hoë bloeddruk met sistoliese waardes bo 200 mmHg en/of diastoliese waardes bo 100 mmHg of hipertensiewe retinale veranderinge van Graad III/IV
- lokale letsels met die risiko vir bloeding (bv. bestaande hemorragiese gastro-intestinale toestande, vorige translumbale aortografie, arteriële punksies, binnespierse inspuitings, inblywende kateters of endotrageale buise)
- na 'n onlangse operasies, (6de tot 10de dag na dag van operasie) afhangende van die omvang van die chirurgie
- onlangse trauma
- onlangse orgaanbiopsie, punksie van die nie-saampersbare vate, intramuskulêre inspuitings of intubasie
- onlangse bevalling of aborsie
- siektes van die urogenitale weg met bestaande of potensiële gevaar vir bloeding (bv. inblywende blaaskateter)
- septiese trombotiese siektes
- vermoede van aterosklerotiese vatdegenerasie, serebrovaskulêre siektes, erge diabetes mellitus, diabetiese/hemorragiese retinopatie
- holtevormende longsiektes (bv. oop tuberkulose) of erge brongitis
- ernstige lewer- of nierskade
- mitraalkleppdefekte of atriale fibrillasie
- endokarditis
- perikarditis: geïsoleerde gevalle van perikarditis, verkeerd as akute miokardiale infarksie gediagnoseer en met FIBREAKER 1 500 000 IU behandel, het tot perikardiale effusie waaronder tamponade gelei
- vorige translumbale aortografie
- probleme met serebrale bloedvloei of onlangse serebrale bloeding

FIBREAKER 1 500 000 IU moet nie tydens swangerskap gegee word nie, veral nie in die eerste 18 weke nie as gevolg van die risiko vir plasentale loslating. Vanweë die hoër waarskynlikheid vir weerstand vanweë antistreptokinaseteenliggame, moet verdere dosisse FIBREAKER 1 500 000 IU nie in die tydperk tussen 5 dae en 12 maande na die aanvanklike dosis gegee word nie.

Lokale toediening:
'n Sistemiese effek is ook na lokale toediening moontlik, afhangende van die volume van die dosis toegedien. Daarom moet die kontraindikasies hierbo genoem ook tydens lokale toediening in ag geneem word.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Bloeding:
FIBREAKER 1 500 000 IU kan bloeding veroorsaak, veral vanaf die plekke van die naaldprik. 'n Dun naald moet gebruik word en die aantal naaldprikke moet beperk word. Bloedvate van die boonste ledemate word verkies in gevalle waar 'n arteriële punksie vir binneaarse terapie nodig is. Na die punktuur moet druk vir ten minste 30 minute toegepas word. 'n Drukverband moet opgesit word en die plek van die punktuur moet gereeld vir tekens van bloeding nagegaan word.

Pasiënte met mitraalkleptdefekte met atriale fibrillasie is meer geneig tot linkerharttrombus wat na trombolitiese terapie tot serebrale embolisme kan lei. Daar is 'n risiko vir retinale bloeding in pasiënte met diabetiese retinopatie.

FIBREAKER 1 500 000 IU is waarskynlik vir die volgende toestande oneffektief:
- diepaartrombose ouer as 14 dae
- okklusie van die sentrale retinale arterie, ouer as 6 tot 8 uur, en trombose van die retinale aar ouer as 10 dae

Die effek kan ook minder wees in pasiënte met onlangse streptokokinfeksie, soos streptokokfaringitis, akute rumatiekkoors of akute glomerulonefritis.

Spesiale voorsorgmaatreëls:
FIBREAKER 1 500 000 IU moet versigtig, indien enigsins, gebruik word in pasiënte met 'n hoër risiko vir bloeding, of diegene in wie bloeding veral gevaarlik kan wees. In gevalle van ernstige bloeding moet behandeling met FIBREAKER 1 500 000 IU gestaak en 'n proteïenaseremmer, bv. aprotinien, teen die volgende dosis gegee word:
Spuit aanvanklik 500 000 KIE tot 1 000 000 KIE (kallikreïeninaktiveerdereenhede) met stadige intraveneuse inspuiting of infusie in (maksimum tempo 5 ml/min). Indien nodig, kan dit elke 4 uur met 200 000 KIE opgevolg word totdat die bloeding stop. Daarbenewens word kombinasie met sintetiese antifibrinolitika aanbeveel. Indien nodig, kan stollingsfaktore vervang word. As akute of terugkerende pulmonêre embolisme tydens behandeling voorkom, moet behandeling met FIBREAKER 1 500 000 IU soos beplan voortgaan om die klonte op te los. Daar is 'n hoër risiko vir bloeding in pasiënte wat antikoagulante of stowwe wat op die vorming of funksie van plaatjies werk ontvang of onlangs ontvang het.

Voordat langtermyn sistemiese lise met FIBREAKER 1 500 000 IU begin, moet tyd gegee word dat die effek van middels wat die vorming of funksie van bloedplaatjies beïnvloed, eers uitwerk. As die pasiënt voorheen heparien ontvang het, moet dit voor trombolitiese behandeling met die toediening van protamiensulfaat geneutraliseer word. Die infusie van FIBREAKER 1 500 000 IU kan dan na 4 ure begin. Die trombientyd moet voor aanvang van behandeling met FIBREAKER 1 500 000 IU nie meer as dubbel die normale kontrolewaarde wees nie. In pasiënte wat voorheen met warfarien behandel is, moet die INR (Internasionale Normaliserende Ratio) minder as 1,7 ('n benaderde protrombienindeks van ten minste 50 %) wees voordat die met infusie van FIBREAKER 1 500 000 IU begin word. Wees versigtig wanneer pasiënte fisies hanteer word. FIBREAKER 1 500 000 IU moet versigtig vir bejaarde pasiënte gebruik word. Teenliggame teen streptokinase word na gebruik van FIBREAKER 1 500 000 IU gevorm, en teenliggaamtiters styg skielik na ongeveer 5 tot 10 dae en keer eers na 6 maande terug na normaal. Hierdie teenliggame kan weerstand of hipersensitiwiteit teen daaropvolgende dosisse van FIBREAKER 1 500 000 IU veroorsaak. Daarom moet verdere dosisse van FIBREAKER 1 500 000 IU nie in die tydperk tussen 5 dae en 12 maande na die aanvanklike dosis gegee word nie (selfs langer tydperke is voorgestel). As trombolitiese behandeling in hierdie tydperk nodig is, moet alternatiewe nie-antigeniese medisyne gebruik word. Met beëindiging van behandeling met FIBREAKER 1 500 000 IU moet die pasiënt antikoagulante kry in 'n poging om terugkeer van trombose te voorkom. Heparien moet verkieslik gegee word, vanaf 4 uur ná die einde van trombolise en dan 'n mondelinge antikoagulante na 14 uur na staking van FIBREAKER 1 500 000 IU. Hoë titers van teenliggame teen streptokinase kan ook na sekere streptokokinfeksies soos streptokokkale faringitis of akute rumatiekkoors in pasiënte voorkom of in diegene met akute glomerulonefritis sekondêr tot streptokokinfeksies. In sulke pasiënte kan daar weerstand teen streptokinase of 'n swakker effek wees. Dit word aanbeveel dat intramuskulêre inspuiting vir die eerste 24 uur vermy word.

Allergiese reaksies teenoor FIBREAKER 1 500 000 IU kan grotendeels voorkom word deur die intraveneuse toediening aanvanklik stadig toe te dien. Kortikosteroïede kan ook profilakties toegedien word (bv. 100 tot 250 mg metielprednisoloon 10 minute voordat met behandeling met FIBREAKER 1 500 000 IU begin word). As 'n allergiese reaksie voorkom, moet die infusie gestaak en die pasiënt met intraveneuse kortikosteroïede saam met adrenalien (epinefrien) en 'n antihistamiene behandel word. Nadat die simptome opgeklaar het, kan met die behandeling voortgegaan word. As 'n anafilaktiese reaksie voorkom, moet die infusie dadelik gestaak en adrenalien (epinefrien) onmiddellik deur stadige intraveneuse inspuiting toegedien word. Daarby kan 'n hoë dosis kortikosteroïede deur stadige intraveneuse inspuiting gegee word.

Invloed op vermoë om motor te bestuur of masjinerie te gebruik:
FIBREAKER 1 500 000 IU sal nie 'n effek hê op die vermoë om 'n voertuig te bestuur of masjinerie te gebruik nie omdat dit in die hospitaal toegedien word.

INTERAKSIES
Daar is 'n hoër risiko vir bloeding in pasiënte wat antikoagulante of stowwe wat die vorming of funksie van bloedplaatjies beïnvloed, ontvang of pas tevore ontvang het (bv. remmers van plaatjieklewing, asetielsalisielsuur, allopurinol, anaboliese steroïede, androgene, skildklierhormone, vlugtige olies, kinidien, klofibraat, fenielbutasoon, indometasien, arielasynsuur- en arielpropioonsuurderivate, tetrasikliene, valproësuur, tiourasiele, sulfoonamiede en dekstraan). Voordat langtermyn sistemiese lise met FIBREAKER 1 500 000 IU begin, moet tyd gegee word dat die effek van middels wat die vorming of funksie van bloedplaatjies beïnvloed, eers uitwerk.
As die pasiënt voorheen heparien ontvang het, moet dit voor trombolitiese behandeling met die toediening van protamiensulfaat geneutraliseer word. Sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS voordat met behandeling voortgegaan word.

SWANGERSKAP EN BORSVOEDING
Swangerskap:
FIBREAKER 1 500 000 IU moet nie in die eerste 18 weke van swangerskap of tydens swaar vaginale bloeding of na onlangse bevalling of aborsie gegee word nie, tensy dit absoluut noodsaaklik is. (Sien KONTRAINDIKASIES).

Borsvoeding:
Die veiligheid tydens borsvoeding is nie bepaal nie.

DOSIS EN GEBRUIKSAANWYSINGS
Metode vir aanmaak:
Natriumchloried 0,9 % (fisiologiese soutwater) is die voorkeur oplosmiddel vir FIBREAKER 1 500 000 IU, hoewel 5 % dekstrose in water gebruik kan word.
1. Spuit 5 ml van die oplosmiddel stadig in die flessie FIBREAKER 1 500 000 IU met die naald se punt teen die kant van die flessie en nie in die medisynepoeier nie. Laat ontspan die gevormde vakuum deur die naald liggies van die spuit los te maak.
2. Kantel die flessie en rol dit liggies. Swaai die inhoud liggies om dit te laat oplos. MOENIE SKUD NIE OM SKUIM TE VERMY.
3. Sodra die poeier heeltemal opgelos is, dra die inhoud van die flessie oor in 45 tot 100 ml van die fisiologiese soutoplossing.
4. MOENIE ENIGE ANDER MEDIKASIE IN DIE FIBREAKER 1 500 000 IU-FLESSIE BYVOEG NIE.
5. Omdat FIBREAKER 1 500 000 IU nie preserveermiddels bevat nie, moet dit onmiddellik voor gebruik aangemaak word.

Dit word voorgestel om 'n intradermale veltoets met 100 IE te doen om vir 'n allergiese reaksie op FIBREAKER 1 500 000 IU te toets. As 'n positiewe reaksie nie na 15 tot 20 minute waargeneem word nie, kan die terapeutiese dosis gegee word.

Toediening:
Vir korttermynlise vir die behandeling van akute miokardiale infarksie:
FIBREAKER 1 500 000 IU word so gou as moontlik binne die eerste 6 uur na aanvang van die infarksie deur binneaarse, intra-arteriële of intrakoronêre infusie toegedien.
Akute veranderende transmurale miokardiale infarksie:
1. Intraveneuse infusie: 1 500 000 IE: FIBREAKER 1 500 000 IU bestaan uit 100 ml fisiologiese sout- of dekstrose-oplossing en word oor 30 tot 60 minute toegedien.
2. Pediatriese gebruik: Daar is nie voldoende ondervinding met behandeling van kinders met FIBREAKER 1 500 000 IU nie.

As hipotensie voorkom, kan dit tydelik beheer word deur die infusie stadiger toe te dien.

NEWE EFFEKTE
Versteurings van bloed en limfatiese stelsel:
Dikwels: Bloeding, waaronder gastrointestinale en lewerbloeding, ruptuur van die milt, urogenitale bloeding
Minder dikwels: Intrakraniale bloeding met hul komplikasies (wat dodelik kan wees) of retroperitoneale bloeding.
Bloeding in die perikardium, waaronder miokardiale ruptuur, kan tydens trombolitiese behandeling van akute miokardiale infarksie voorkom.
Bloeding kan in alle weefsel en organe van die liggaam voorkom met simptome in enige liggaamstelsel, waaronder die buik, kardiovaskulêre stelsel, gewrigte en SSS. Bloeding moet gesien word as 'n moontlike oorsaak van ongewone simptome wat na toediening kan voorkom.

Hartversteurings:
Minder dikwels: Kardiale disritmie, miokardiale infarksie, aanhoudende angina pectoris en hartversaking, wat moontlik tot hart- en respiratoriese arres kan lei. Kardiovaskulêre hipoksie, bradikardie.

Oogversteurings:
Minder dikwels: Uveïtis en okklusie van die retinale slagaar, iritis, retinale bloeding.

Hepato-bilière versteurings:
Dikwels: Kortstondige toenames in die waardes van lewerfunksietoetse of bilirubien. Geelsug, lewerhematoom.
Minder dikwels: Respiratoriese, toragiese en mediastinale versteurings. Noodlottige akute respiratoriese noodsindroom (as gevolg van allergiese reaksies).

Vaskulêre versteurings:
Dikwels: Hipotensie. As hipotensie voorkom, kan dit tydelik beheer word deur die infusie stadiger toe te dien.
Minder dikwels: Akute of herhalende pulmonale embolisme. Die opbreek van bestaande bloedklonte kan soms emboli elders veroorsaak. Vaskulitis. Niekardiogeniese pulmonêre edeem. Cholesterolembolisme. Hemorragiese of trombo-emboliese beroerte. Gangreenagtige tone/vingers. Hipertensie.

Gastrointestinale versteurings:
Minder dikwels: Gastrointestinale bloeding, retroperitoneale bloeding, ruptuur van die milt. Ingewandsinfarksie. Naarheid en braking, buikpyn.

Versteurings van endokrienstelsel:
Minder dikwels: Pankreatitis.

Algemene versteurings en toestande by die plek van toediening:
Dikwels: Bloeding by die plekke van die naaldprik. Koors en kouekoors. Laerug en abdominale pyn. Hoofpyn, astenie en ongesteldheid.

Versteurings van die immuunstelsel:
Dikwels: Ontwikkeling van teenliggame teen streptokinase. Allergiese reaksies, bv. veluitslag, gloede of rooiheid van die vel, dispnee, edeem, brongospasma, soms simptome van anafilakse en serumsiekte, galbulte of jeuk, moeilike asemhaling of hyg.
Minder dikwels: "Perstoonsindroom".

Versteurings van vel en subkutane weefsel:
Minder dikwels: Livedo reticularis (persrooi, netagtige, los kolle op die vel). Veluitslag, galbulte.

Muskuloskeletale versteurings en van die bindweefsel:
Dikwels: Muskuloskeletale pyn, soos rugpyn.
Minder dikwels: Artritis. Rabdomiolise.

Versteurings van die senustelsel:
Minder dikwels: Neuro-allergiese simptome (Guillain-Barrésindroom, polineuropatie). Serebrale stuiptrekkings. Serebrale of rugmurginfarksie. Hoofpyn. Serebrale bloeding.

Versteurings van die niere en urienweg:
Minder dikwels: Nefritis. Akute nierversaking.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
In geval van onopsetlike oordosering is die behandeling simptomaties en ondersteunend.

IDENTIFIKASIE
'n Wit poeier of 'n wit bros soliede koek in helder glasflessies van 12 ml verseël met 'n prop van grys broombutielrubber met 'n lemmetjiegroen aluminium afwipseël.

AANBIEDING
'n Wit poeier of 'n wit bros soliede, higroskopiese koek verpak in 'n gestandaardiseerde 8R-spuitglasflessie van 12 ml verseël met 'n prop van grys broombutielrubber en bedek met 'n lemmetjiegroen aluminium afwipseël. Flessies word individueel in kartonne verpak.

BERGINGSINSTRUKSIES
Bêre tussen 2 en 8 °C. Moenie vries nie. Beskerm teen lig.
Die droë stof moet nie na die vervaldatum wat op die pak en houer gedruk is, gebruik word nie.
Die oplossing moet dadelik nadat dit aangemaak is, gebruik word.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
44/31/0010

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Gen-Eye (Edms) Bpk[1]
Eenheid 7, Royal Palm Sake Landgoed
Washingtonstraat 646, Halfway House
Midrand, 1685
Gauteng, Suid-Afrika
[1] Maatskappyregistrasienommer: 2009/009360/07

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET
Datum van registrasie: 23 November 2017
Datum van huidige hersiende voubiljet deur SAHPRA goedgekeur: 19 Oktober 2021

FIB/PI/03/09.2021
Pro-Print

PASIëNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM

FIBREAKER 1 500 000 IU Inspuiting

Streptokinase 1 500 000 IE

Lees hierdie hele pamflet sorgvuldig deur voordat FIBREAKER 1 500 000 IU aan u gegee word.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, vra asseblief vir u dokter of u apteker.
- FIBREAKER 1 500 000 IU is vir u persoonlik voorgeskryf en u moet nie u medisyne aan ander mense gee nie. Dit kan hulle skade aandoen, selfs al is hulle simptome dieselfde as u s'n.

1. WAT FIBREAKER 1 500 000 IU BEVAT
Die aktiewe bestanddeel is 1 500 000 IE streptokinase per flessie.
Die ander bestanddele is menslike albumien en poligelien.

2. WAARVOOR FIBREAKER 1 500 000 IU GEBRUIK WORD
FIBREAKER 1 500 000 IU is 'n hoogs gesuiwerde proteïen wat fibrienbloedklonte en ander plasmaproteïene verteer.
Dit word gebruik om die volgende toestande in volwassenes te behandel:
- Wanner 'n bloedklont in die hartspier gevorm het en bloedvoorsiening aan die deel verhinder.

3. VOORDAT U FIBREAKER 1 500 000 IU KRY
Moenie FIBREAKER 1 500 000 IU kry nie:
- as u ernstige allergiese reaksies teenoor streptokinase of enige van die ander bestanddele van FIBREAKER 1 500 000 IU het
- as u inwendige bloeding van maagsere of letsels het of onlangs gehad het
- as u bloed geneig is om klonte te vorm
- as u inflammasie van die pankreas het
- as u onlangs (in die afgelope 10 dae) 'n operasie ondergaan het
- as u ly aan hoë bloeddruk (onbeheer) of as u maklik bloei
- as u onlangs 'n beroerte gehad het
- as u esofageale spatare (vergrote are van die onderste slukderm) het
- as u 'n breingewas het
- as u onlangs trauma aan u kop of ander trauma gehad het
- as u onlangs 'n orgaanbiopsie, punksie van die niesaampersbare vate, intramuskulêre inspuitings of intubasie gehad het
- as u onlangs 'n bevalling of aborsie gehad het
- as u enige siekte van die urogenitale sisteem (geslagsorgane en die urinêre stelsel) met bestaande of potensiële bronne van bloeding het
- as u vermoed dat u dalk aterosklerose (opbou van neerslag in die are), enige toestand wat die sirkulasie van bloed na die brein raak, erge diabetes of skade aan die retina van die oog het
- as u holtevormende longsiektes (bv. oop tuberkulose) of erge brongitis het
- as u nier- of lewerskade het
- as u enige hartklepdefekte of enige hartritmeversteurings het
- as u endokarditis (inflammasie van die binneste laag van die hart) het
- as u perikarditis (inflammasie van die fibreuse sak rondom die hart) het
- as u voorheen 'n translumbale aortografie gehad het (inspuiting van kontrasmiddel, terwyl X-strale van die aorta neem word)
- as u in die eerste 18 weke van swangerskap is

FIBREAKER 1 500 000 IU inspuiting moet nie aan kinders gegee word nie.

Lokale toediening:
U dokter sal die bogenoemde kontraindikasies vir plaaslike toediening oorweeg omdat 'n sistemiese effek ook na plaaslike toediening moontlik is.

Wees besonder versigtig met FIBREAKER 1 500 000 IU:
- as daar 'n hoër risiko vir bloeding is of as dit baie gevaarlik vir u sal wees om te bloei
- as u medikasie om stolling van bloed te voorkom gebruik of onlangs gebruik het
- as u enige hartklepdefekte het wat met hartritmeversteurings verband hou
- as u skade aan die retina het wat deur diabetes veroorsaak word
- as u bejaard is

Swangerskap en borsvoeding:
U moet nie 'n FIBREAKER 1 500 000 IU inspuiting tydens die eerste 18 weke van swangerskap kry nie of tydens swaar vaginale bloeding of net na 'n bevalling of aborsie of as u u baba borsvoed.

Motorbestuur en gebruik van masjinerie:
FIBREAKER 1 500 000 IU sal nie 'n effek hê op die vermoë om 'n voertuig te bestuur of masjinerie te gebruik nie omdat dit in die hospitaal toegedien word.

Gebruik van ander medisyne saam met FIBREAKER 1 500 000 IU:
Sê altyd vir u gesondheidskundige as u enige ander medisyne gebruik. Dit sluit komplementêre en tradisionele medisyne in. As u medisyne kry wat bloedstolling voorkom of onlangs gekry het of stowwe wat op die vorming of funksie van plaatjies werk, raadpleeg u dokter omdat u 'n hoër risiko vir bloeding kan hê. Voorbeelde van sulke medisyne is remmers van plaatjieklewing, asetielsalisielsuur, allopurinol, anaboliese steroïede, androgene, skildklierhormone, vlugtige olies, kinidien, klofibraat, indometasien, arielasynsuur- en arielpropioonsuurderivate, tetrasikliene, valproësuur, tiourasiele, sulfoonamiede en dekstraan.

4. HOE OM FIBREAKER 1 500 000 IU TE KRY
Dit sal nie van u verwag word om FIBREAKER 1 500 000 IU aan uself te gee nie. Dit sal aan u gegee word deur 'n persoon wat bevoeg is om dit te doen.

As u meer FIBREAKER 1 500 000 IU ontvang het as wat u moes:
Omdat 'n gesondheidskundige FIBREAKER 1 500 000 IU sal toedien, sal hy/sy die dosis beheer. In geval van oordosering, sal u dokter die oordosering egter bestuur.

5. MOONTLIKE NEWE EFFEKTE
FIBREAKER 1 500 000 IU kan newe effekte hê. Die mees algemene newe effekte is bloeding uit onlangse snye, wonde, letsels of sere en bloeding by die inspuitplek. Nie al die newe effekte wat vir FIBREAKER 1 500 000 IU aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand agteruitgaan terwyl u FIBREAKER 1 500 000 IU gebruik, moet u u dokter, apteker of ander gesondheidskundige asseblief om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om FIBREAKER 1 500 000 IU te kry en onmiddellik vir u dokter sê:
- Probleme met asemhaling.
- Veluitslag.
- Gloede of rooiheid van die vel.
- Galbulte of jeuk.
- Vloeistofretensie in die liggaam (swelling).

Dit is almal baie ernstige newe effekte. As u dit ervaar, kan dit wees dat u 'n ernstige allergiese reaksie teenoor FIBREAKER 1 500 000 IU het. U mag dringende mediese aandag of hospitalisasie nodig hê.

Sê dadelik vir u dokter as u enige van die volgende opmerk:
- Probleme met asemhaling.
- Hartaanval of hartversaking.
- Pyn in die borskas.
- Gebrek aan suurstof na die hart.
- Inflammasie van die oog (uveïtis of iritis).
- Verlies van visie (retinaleslagaarokklusie).
- Bloeding van die oë (retinale bloeding).
- Stygings in die waardes van lewerfunksietoetse of bilirubien.
- Geel verkleuring van die vel en/of oë (geelsug).
- Abdominale pyn (lewerhematoom).
- Bloedklonte elders.
- Inflammasie wat bloedvate vernietig (vaskulitis).
- Vloeistof in die longe (pulmonêre edeem).
- Cholesterol wat bloedvate verstop (cholesterolembolisme).
- Liggaamsweefsel van tone/vingers wat sterf (gangreentone/vingers).
- Inflammasie van die pankreas (pankreatitis).
- Koors en kouekoors.
- Laerugpyn.
- Ontwikkeling van teenliggame teen streptokinase.
- Verkleuring van die tone ("perstoonsindroom").
- Persrooi, netagtige, los kolle op die vel (livedo reticularis).
- Afbraak van beskadigde skeletspierweefsel (rabdomiolise).
- Toevalle (serebrale konvulsies).
- Afsterf van weefsel in die brein of rugmurg (serebrale of rugmurginfarksie).
- Bloeding op die brein (serebrale bloeding).
- Inflammasie van die niere (nefritis).
- Nierversaking.

Dit is almal ernstige newe effekte. U mag mediese aandag nodig hê.

Sê vir u dokter as u enige van die volgende opmerk:
- Moegheid, swakheid, duiseligheid en floute (bradikardie).
- Naarheid en braking.
- Hoofpyn en algemene ongemak (malaise).
- Inflammasie van die gewrigte (artritis).
- Swakheid, gevoelloosheid, naalde-en-spelde en brandpyn (polineuropatie).

As u enige newe effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief daarvan sê.

6. BERGING EN WEGDOENING VAN FIBREAKER 1 500 000 IU
HOU BUITE BEREIK VAN KINDERS.
FIBREAKER 1 500 000 IU word gewoonlik in u dokter se spreekkamers of hospitaal gestoor.
Dit moet in 'n yskas tussen 2 en 8 °C gehou word. Moenie vries nie. Beskerm teen lig.
Bêre in die oorspronklike verpakking.
Hou die flessie in die karton.
Die droë stof moet nie na die vervaldatum wat op die etiket en karton gedruk is, gebruik word nie.
Die oplossing moet dadelik nadat dit aangemaak is, gebruik word.
Die dokter wat FIBREAKER 1 500 000 IU inspuiting gee sal die gebruikte flessie in 'n houer vir skerp voorwerpe weggooi.

7. AANBIEDING VAN FIBREAKER 1 500 000 IU
'n Wit poeier of 'n wit bros soliede, higroskopiese koek verpak in 'n gestandaardiseerde 8R-spuitglasflessie van 12 ml verseël met 'n prop van grys broombutielrubber en bedek met 'n lemmetjiegroen aluminium afwipseël. Flessies word individueel in kartonne verpak.

8. IDENTIFIKASIE VAN FIBREAKER 1 500 000 IU
'n Wit poeier of 'n wit bros soliede koek in helder glasflessies van 12 ml verseël met 'n prop van grys broombutielrubber met 'n lemmetjiegroen aluminium afwipseël.

9. REGISTRASIENOMMER/VERWYSINGSNOMMER
44/31/0010

10. NAAM EN ADRES VAN REGISTRASIEHOUER
Gen-Eye (Edms) Bpk[1]
Eenheid 7, Royal Palm Sake Landgoed
Washingtonstraat 646, Halfway House
Midrand, 1685
Gauteng, Suid-Afrika
[1] Maatskappyregistrasienommer: 2009/009360/07

11. DATUM VAN PUBLIKASIE
Datum van registrasie: 23 November 2017
Datum van huidige hersiende pasiëntinligtingsblad deur SAHPRA goedgekeur: 19 Oktober 2021

FIB/PIL/03/09.2021
Pro-Print

PRO-PRINT (PTY) LTD
THE PROFESSIONALS IN PRINT

REPRO

Date:	25th October 2021
Operator:	Claudette Isaacs
Customer:	Gen Eye
Product Name:	Fibreaker 1 500 000 IU Injection PI/PIL
Product Code:	FIB/PI/03/09.2021 FIB/PIL/03/09.2021
Dimensions:	330 x 350 mm
Fold Size:	165 x 29 mm
Fond Size:	6 point Helvetica Condensed
Colours: (1)	Black
	--
Barcode:	--
Pharmacode:	--
Stock:	--
Proof Status:	4th (Fourth)

Proof read by: _____

Reset: ☐ **Alterations:** ☑ **Disk/Possie:** ☐

No alterations – proceed as soon as possible ☐

Note alterations – Further proof is required ☐

PLEASE CHECK CAREFULLY.

Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

Signature: ..... **Date:**.....

PROOF NOT READ – NO COPY SUPPLIED ☐