health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Mr E van Zyl
Equity Pharmaceuticals (Pty) Ltd
100 Sovereign Road
Route 21 Corporate Park
Nellmapius Drive
Irene
Pretoria

Dear Mr van Zyl

Section 21 Extension Authorization for STREPTOKINASE 1.5MU INJECTION

Attached, please find the Authorization for exemption under Section 21 of the Medicines and Related Substances Act by SAHPRA granted for:

- **Streptokinase 1.5MU Injection**

The quantities for which approval was granted are only estimates based on procurement by provinces over the last 6 months. Please note that the National Department of Health (NDOH) cannot guarantee the procurement of these quantities, as NDOH has no control over orders being placed by provincial depots, and current stock holding might influence estimated quantities.

The following process will be followed to ensure the quality of the product being brought in:

1. Manufacturer will submit an assay and identification of every batch imported.
2. An additional assay of every batch will be done by a quality control laboratory.
3. A random sample will be assayed during the authorized period by a quality control laboratory.
4. Aggregate statistics to be submitted to NDOH in the first week of each month of all orders received and quantities supplied per province.
5. The NDOH needs to be advised of the quantities and date of arrival of stocks in terms of this authorization within 7 days after arrival.
6. The supplier will provide monthly reports, by the 7th of each month, using the attached format of orders received and issues done.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.

8. The full quantities imported in terms of this Section 21authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent overstocking once the contracted supplier gets back into stock.

It should be noted this authorization applies only for use of the product in the public sector with estimated usage quantities for a period of one month. The authorization is expected to expire on **06 March 2027**.

Table 1: Provincial estimates

Province	Six Months Estimate	Uptake
DCS	0	0
EC-MT	30	0
EC-PE	300	0
FS	20	0
GP	36	0
KZN	100	100
LP	0	0
MP	12	12
NC	0	0
NW	0	0
SAMHS	0	0
WC	225	305
Total	**723**	**417**

Yours sincerely

K Jamaloodien

KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 14/9/2026

S2100037138

SAHPRA Head Office
Building A, Loftus Park
2nd Floor
Kirkness Street
Arcadia
0083

Section 21 Outcome Letter

2026-09-10

Ms Khadija Jamaloodien

Voortrekker Road, Dr AB Xuma, M24, Voortrekker Road, Pretoria, Gauteng, Tshwane, Gauteng, South Africa, 0157

Tshwane

buhle.mbongo@health.gov.za

Dear Ms Khadija Jamaloodien

REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND CONTROLLED SUBSTANCES ACT, 1965 (ACT 101 of 1965):

Your application dated **2026-09-07** refers

A. STATUS: Approved

B. APPLICANT: Ms Khadija Jamaloodien

C. IMPORTING COMPANY: EQUITY PHARMACEUTICAL (PTY) LTD

D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 1

E. UNREGISTERED MEDICINES: GENERIC NAME (INN / ACTIVE INGREDIENT): Streptokinase for Injection BP

F. TRADE NAME: Streptokinase for Injection BP 1.5 MU

G. QUANTITY: 336 Packs (1)

SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A, Loftus Park
2nd Floor
Kirkness Street
Arcadia
0083

H. LETTER NUMBER: S2100037138

Section 21 authorization letters are valid for a period of 6 months from the letter date, unless otherwise specified.

A progress report must be submitted once treatment is completed or on a reauthorization request

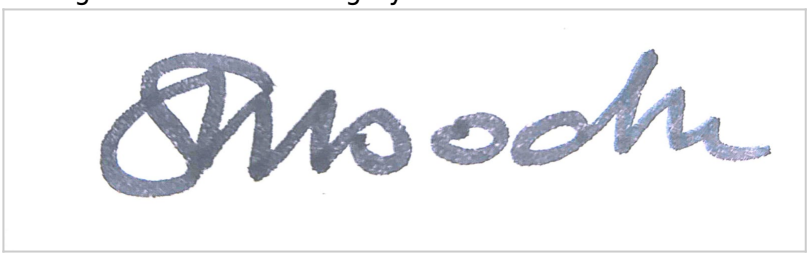
Comments:

No Data

Yours faithfully,

Shyamli Munbodh

Manager: Section 21 Category A Medicines



health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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REQUEST FOR QUOTATION FORM

- **Instruction to complete this Request for Quotation (RFQ)**
  PLEASE PROVIDE A QUOTE FOR THE FOLLOWING PRODUCT(S).
  PLEASE QUOTE ON THIS RFQ FORM AND ATTACH YOUR QUOTE WITH THE REQUESTED DETAILS.
  THE SECTIONS HIGHLIGHTED IN YELLOW MUST BE COMPLETED BY THE SUPPLIER.
- **THIS DOES NOT CONSTITUTE ANY OBLIGATION TO PROCURE THE ITEM AS THIS WILL BE SUBMITTED FOR CONSIDERATION TO PROVINCIAL PROCUREMENT UNITS. IT MAY ALSO SERVE AS A BUY OUT AGAINST CURRENT NON-COMPLIANT SUPPLIERS.**

ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED

REFERENCE NUMBER:	NORMAL		SECTION 21	X	**S21RFQ169**
QUOTE ENQUIRY DATE	**18/02/2026**	QUOTE CLOSING DATE			**01/03/2026**
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE *(SCM Practitioner to Specify if applicable)*					

REQUESTING INSTITUTION CONTACT DETAILS

NAME OF REQUESTOR	Buhle Mbongo		
EMAIL ADDRESS	Buhle.Mbongo@health.gov.za		
PHONE No.	**012 395 9539**	FAX No.	**N/A**

PRODUCT INFORMATION

DESCRIPTION PER MPC	**STREPTOKINASE 1.5IU INJCETION**		
TRADE DESCRIPTION	Streptokinase for Injection BP 1500 000IU		
UNIT OF MEASURE	**1's**	PACK or BOX (*SIZE/ QUANTITY*)	**1's**
QUANTITY REQUIRED	**750 Vials**		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

COMPANY NAME	Equity Pharmaceuticals (PTY) Ltd			
SUPPLIER NUMBER	MAAA007480			
SUPPLIER CODE (NDoH)				
CONTACT PERSON 1	NAME	**Ehrard van Zyl**		
	PHONE	**012 345 1747**	FAX	**012 345 1412**
	MOBILE	*072 040 8511*		
	E-MAIL	**ehrard@equitypharma.co.za**		
CONTACT PERSON 2	NAME	**Hannes Strydom**		
	PHONE	**012 345 1747**		
	MOBILE	*0826161954*		

	E-MAIL	hannes@equitypharma.co.za	
QUOTE DETAILS			
PRICE PER VIAL (INCL. VAT)	R 286.35	TOTAL PRICE (INCL. DELIVERY & VAT)	R 214 762.50
*STOCK'S EXPIRY DATE(SHELF-LIFE)	18 months		
VOLUMES AVAILABLE – 7DAYS			
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS	750		
VOLUMES AVAILABLE - 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	180 days		
NORMAL LEAD/DELIVERY TIME	3 days		
DEVIATION TO SPECIFICATION			
COMMENTS:			
DECLARATION BY SUPPLIER			
I hereby declare that in submitting this bid, there has been no consultation, communication, agreement or arrangement with any competitor/supplier regarding the price, quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.			
NAME			
CAPACITY	**Business Unit Manager: Specialist Medicine**		
SIGNATURE *(OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)*			
DATE	**27/02/2026**		

PROVINCIAL ESTIMATES	
Province	**Six Months Estimate**
DCS	0
EC-MT	30
EC-PE	300
FS	20
GP	36
KZN	100
LP	0
MP	12
NC	0
NW	0
SAMHS	0
WC	225

Please submit quotations to Section21Quotes@health.gov.za

Please ensure that you include the following as part of the Quotation:

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Quotation on Official Company Letterhead
- Central Supplier Database Summary Report (CSD), updated for the current month
- Medicine Registration Certificate (Only for Locally Registered Products)
- *Artwork/Labelling
- *Package Insert: (Please attach)
- *Manufacturer Certificate: (Please attach)
- *Country of Origin: (Please indicate)

*Additional items required when submitting a quote for a Section 21 Item (Unregistered Medicine)
All the above is required to expedite the process of reviewing the quotation.

Please ***SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD***

NB:

- *The supplier submitting the quotation must be the same entity with which the provinces will place their orders.
- The size of each individual attachment must not be more than 2MB (you may attach multiple files in one email but collectively they should not be more than 2MB in size).
- Please ensure that you provide all prescribed documentation that is outlined on page two of this RFQ form.
- The confirmation letter from manufacturer to supply South Africa with Bivalent Oral Poliomyelitis Vaccine (bOPV) must be provided (only *in cases of a Bivalent Oral Poliomyelitis Vaccine RFQ*).
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in a pdf or word format only.
- All prices must please be submitted in two decimals and in ZAR.
- If submitting more than one quotation, please make sure that your subject line includes e.g., 1 of 2 or 1 of 3 etc.
- Any submission with missing required documentation shall not be considered.
- Any submission with blurry required documents shall not be considered.
- The only electronic GMP Certificate considered is that from EUDRA.
- CSD must be updated for the current month of the RFQ date.
- **Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.**

SUBMIT BOTH COMPLETED RFQ FORM AND QUOTATION

27/02/2026

Equity Pharmaceuticals (Pty) Ltd.
1997/009942/07

+27 12 345 1747
+27 12 345 1412
equity@equitypharma.co.za

www.clinigengroup.com
www.equitypharma.co.za

QUOTATION # 20260227/1

TO: National Department of Health

TEL : 012 395 9539
FAX :
Email : Section21Quotes@health.gov.za

CONTACT PERSON / PATIENT : Buhle Mbongo

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	TOTAL INCL
	Streptokinase for injection BP 1 500 000IU	1 x Vial	1	R 249.00	R 286.35
			750	**R 186 750.00**	**R 214 762.00**
			750	**R 186 750.00**	**R 214 762.00**

Valid for 180 days

Employee Signature: _____

Date: 27/02/2026

Approved by: Ehrard van Zyl

EQUITY
PHARMACEUTICALS

Equity Pharmaceuticals (Pty) Ltd.
1997/009942/07

+27 12 345 1747
+27 12 345 1412
equity@equitypharma.co.za

www.clinigengroup.com
www.equitypharma.co.za

27/02/2026

National Department of Health

Directorate: Affordable Medicines

E-mail: Section21Quotes@health.gov.za

Attention: Ms Buhle Mbongo

Dear Ms Mbongo

Re: Request for quotation – Streptokinase 1.5IU Injection– Section 21 Supply

Trust you are well. Please find below our quotation for Streptokinase for injection BP 1500 000IU supplied under section 21 terms.

• Quantity:	**750 vials**
• Delivery Time (Weeks):	**5 weeks**
• Price (Vat Inclusive):	**R 286.35 incl. vat per vial**
• Generic Name:	**Streptokinase 1.5IU injection**
• Trade Name:	**Streptokinase for injection BP 1500 000IU**
• Packaging:	**1 vial**
• Specifications:	**1 500 000 IU / Vial**
• Shelf Life:	**18 months**
• Package Insert:	**Please find attached**
• Manufacturer:	**Kwality Pharmaceuticals Ltd.**
• Country of Origin:	**India**

Please note that the immediate availability of the product is conditioned on the manufacturer receiving notice of our order as soon as possible. Unfortunately, the stock cannot be reserved for our purposes for too long.

We look forward to your response.

Please contact me if you require any additional information.

Kind Regards

Ehrard van Zyl

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Streptokinase For Injection BP 1500000 IU

2. Qualitative and quantitative composition

Each vial contains:

Streptokinse Concentrated Solution BP……1500000 IU

3. Pharmaceutical form

Lyophilized powder for injection

4. Clinical particulars

4.1 Therapeutic indications

Streptokinase For Injection BP is indicated in adults.

Acute myocardial infarction: within 12 hours of onset with persistent ST-segment elevation or recent left bundle-branch block. Note: No statement on therapy outcome can be made for administration beyond the time window indicated above.

4.2 Posology and method of administration

Posology

Paediatric population

The safety and efficacy of Streptokinase For Injection BP have not been sufficiently established in children. Due to low levels of plasminogen in newborns and in children with acquired plasminogen deficiency and due to the potential of streptokinase for allergic/anaphylactic reactions, it is not recommended in neonates, infants and children.

Adults

Systemic administration: A single dose of 1.5 million IU streptokinase should be infused intravenously over one hour.

Local intracoronary administration: A bolus of 20,000 IU streptokinase should be followed by a maintenance infusion of 2,000 IU to 4,000 IU per minute over 30 to 90 minutes depending on the achievement of coronary artery patency.

Method of Administration

The administration of streptokinase may be intravenous or intracoronary.

For instructions on reconstitution of the medicinal product before administration, see section 6.6.

Upon reconstitution with physiological saline a clear solution, colourless to yellowish, is obtained.

Note: When thrombolytic therapy is necessary and a high antibody concentration against streptokinase is present or when recent streptokinase therapy has been given (more than 5 days and less than one year previously), homologous fibrinolytics should be used (see sections 4.4 and 4.8).

Adjuvant treatment

Treatment with aspirin (150 mg daily) for at least 4 weeks is recommended for prophylaxis after streptokinase therapy for acute myocardial infarction. The first dose should be given as soon as possible after the myocardial infarction.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Contraindications to treatment with Streptokinase For Injection BP, because of the increased risk of haemorrhage under thrombolytic therapy, include:

- existing or recent internal haemorrhage

- all forms of reduced blood coagulability, in particular spontaneous fibrinolysis and extensive clotting disorders

- recent cerebrovascular accident, intracranial or intraspinal surgery

- intracranial neoplasm

- recent head trauma

- arteriovenous malformation or aneurysm

- known neoplasm with risk of haemorrhage

- acute pancreatitis

- uncontrollable hypertension with systolic values over 200 mm Hg and/or diastolic values over 100 mm Hg or hypertensive retinal changes Grades III/IV

- recent implantation of a vessel prosthesis

- simultaneous or recent treatment with oral anticoagulants (INR >1.3)

- severe liver or kidney damage

- endocarditis or pericarditis. Isolated cases of pericarditis, misdiagnosed as acute myocardial infarction and treated with streptokinase, have resulted in pericardial effusions including tamponade

- known haemorrhagic diathesis

- recent major operations (6^{th} to 10^{th} post-operative day, depending on the extent of the procedure)

- invasive operations, e.g. recent organ biopsy, long-term (traumatic) closed chest cardiac massage

4.4 Special warnings and precautions for use

The following conditions would normally be considered contraindications to streptokinase therapy, but in certain situations the benefits could outweigh the potential risks:

- recent severe gastrointestinal bleeding, e.g. active peptic ulcer

- risk of severe local haemorrhage, e.g. in case of translumbar aortography

- recent trauma and cardiopulmonary resuscitation

- invasive operations, e.g. recent intubation

- puncture of non-compressible vessels, intramuscular injections, large arteries

- recent abortion or delivery

- pregnancy (see section 4.6)

- diseases of the urogenital tract with existing or potential sources of bleeding (implanted bladder catheter)

- known septic thrombotic disease

- severe arteriosclerotic vessel degeneration, cerebrovascular diseases

- cavernous pulmonary diseases, e.g. open tuberculosis or severe bronchitis

- mitral valve defects or atrial fibrilation

- aortic dissection

- diabetic retinopathy increase risk of local bleeding

Antistreptokinase

Repeat treatment with streptokinase administered more than 5 days and less than 12 months after initial treatment may not be effective. This is because of the increased likelihood of resistance due to antistreptokinase antibodies.

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

Infusion rate and corticosteroid prophylaxis

At the beginning of therapy, a fall in blood pressure, tachycardia or bradycardia (in individual cases going as far a shock) are commonly observed. Therefore, at the beginning of therapy the infusion should be performed slowly.

Corticosteroids can be administered prophylactically to reduce the likelihood of infusion-related allergic reactions.

Pre-treatment with heparin or coumarin derivatives

If the patient is under active heparinization, it should be neutralised by administering protamine sulphate before the start of the thrombolytic therapy. The thrombin time should not be more than twice the normal control value before thrombolytic therapy is started. In patients previously treated with coumarin derivatives, the INR (International Normalized Ratio) must be less than 1.3 before starting the streptokinase infusion.

Simultaneous treatment with acetylsalicylic acid

Recent evidence indicates that controlled-dose adjuvant acetylsalicyclic therapy in combination with streptokinase is capable of improving the response in the management of acute myocardial infarction. See also section 4.2.

Streptokinase is not indicated for restoration of patency of intravenous catheters.

4.5 Interaction with other medicinal products and other forms of interaction

There is an increased risk of haemorrhage in patients who are receiving or who have recently been treated with anticoagulants, e.g. heparin or drugs which inhibit platelet formation or function, e.g. platelet aggregation inhibitors, dextrans.

4.6 Fertility, pregnancy and lactation

Streptokinase For Injection BP is contraindicated in pregnancy. There is no evidence of the drug's safety in pregnancy, nor is there evidence from animal work that it is free from hazard. Bleeding and anaphylactic reactions might cause abortion and foetal death, especially when streptokinase is given within the first 18 weeks of pregnancy. Use only when there is no safer alternative.

It is unknown whether streptokinase is excreted in human milk. Breast milk should be discarded during the first 24 hours following thrombolytic therapy.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The following adverse reactions are based on clinical trial and post-marketing experience. The following standard categories are used:

Very common	more than1/10
Common	more than 1/100; less than 1/10
Uncommon	more than 1/1000; less than 1/100
Rare	more than 1/10,000; less than 1/1000
Very Rare	less than 1/10,000 (including isolated cases)

Blood and lymphatic system disorders

Common: haemorrhage at the injection site, ecchymoses, gastrointestinal bleeding, genitourinary bleeding, epistaxis

Uncommon: cerebral haemorrhages with their complications and possible fatal outcome, retinal haemorrhages, severe haemorrhages (also with fatal outcome), liver haemorrhages,

retroperitoneal bleeding, bleeding into joints, splenic rupture. Blood transfusions are rarely required.

Very rare: haemorrhage into the pericardium including myocardial rupture during thrombolytic treatment of acute myocardial infarction

In serious haemorrhagic complications, streptokinase therapy should be discontinued and a proteinase inhibitor, e.g., aprotinin, should be given as follows. Initially 500 000 KIU (Kallikrein Inactivator Unit) up to one million KIU by slow intravenous injection or infusion. If necessary this should be followed by 200,000 KIU every four hours by intravenous drip until the bleeding stops. In addition, combination with synthetic antifibrinolytics is recommended. If necessary, clotting factors can be substituted. Additional administration of synthetic antifibrinolytics has been reported to be efficient in single cases of bleeding episodes.

Immune system disorders

Very Common: development of antistreptokinase antibodies (see also 4.4)

Common: allergic anaphylactic reactions, e.g. rash, flushing, itching, urticaria, angioneurotic oedema, dyspnoea, bronchospasm, hypotension

Very Rare: delayed allergic reactions, e.g. serum sickness, arthritis, vasculitis, nephritis, neuroallergic symptoms (polyneuropathy, e.g. Guillain Barré syndrome), severe allergic reactions up to shock including respiratory arrest.

Allergic reactions can largely be avoided by giving the infusion slowly. Moderate or mild allergic reactions can be managed with concomitant antihistamine and/or corticosteroid therapy. If a severe allergic reaction occurs the infusion of streptokinase should be discontinued immediately and the patient given the appropriate treatment. The current medical standards for shock treatment should be observed. Lysis therapy should be continued with homologous fibrinolytics, such as Urokinase or tPA.

Nervous system disorders

Rare: neurologic symptoms (e.g. dizziness, confusion, paralysis, hemiparesis, agitation, convulsion) in the context of cerebral haemorrhages or cardiovascular disorders with hypoperfusion of the brain

Eye disorders

Very rare: iritis/uveitis/iridocyclitis

Cardiac and vascular disorders

Common: at the start of therapy, hypotension, tachycardia, bradycardia

Very rare: crystal cholesterol embolism

During fibrinolytic therapy with streptokinase in patients with myocardial infarction, the following events have been reported as complications of myocardial infarction and/or symptoms of reperfusion:

Very common: hypotension, heart rate and rhythm disorders, angina pectoris

Common: recurrent ischaemia, heart failure, reinfarction, cardiogenic shock, pericarditis, pulmonary oedema

Uncommon: cardiac arrest (leading to respiratory arrest), mitral insufficiency, pericardial effusion, cardiac tamponade, myocardial rupture, pulmonary or peripheral embolism

These cardiovascular complications can be life-threatening and may lead to death.

During local lysis of peripheral arteries, distal embolization cannot be excluded.

Respiratory Disorders

Very rare: non-cardiogenic pulmonary oedema after intracoronary thrombolytic therapy in patients with extensive myocardial infarction

Gastrointestinal disorders

Common: nausea, diarrhoea, epigastric pain, vomiting

General disorders and administration site conditions

Common: headache, back pain, musculoskeletal pain, chills, fever, asthenia, malaise

Testing

Common: Transient elevations of serum transaminases and bilirubin

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important.

4.9 Overdose

Long-term overdosage of streptokinase may induce the risk of rethrombosis by prolonged decrease of plasminogen. See also section 4.8 and 5.1.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Streptokinase (antithrombotic agents, enzymes)

ATC code: B01A D01

Streptokinase For Injection BP is a highly purified streptokinase derived from β haemolytic streptococci of Lancefield group C. The activation of the endogenous fibrinolytic system is initiated by the formation of a streptokinase-plasminogen complex.

This complex possesses activator properties and converts plasminogen into the proteolytic and fibrinolytic active plasmin. The more plasminogen that is bound within this activator complex, the less plasminogen is left to be converted into its enzymatically active form. Therefore, high doses of streptokinase are associated with a lower bleeding risk and vice versa.

After intravenous administration and neutralisation of the individual antistreptokinase-antibody titre, streptokinase is immediately available systemically for activation of the fibrinolytic system.

Streptokinase has a very short half-life. The first rapid clearance from the plasma is due to the formation of the complex between streptokinase and streptokinase antibody. This complex is biochemically inert and is cleared rapidly from the circulation. Once the antibody has been neutralised, the streptokinase activates the plasminogen as described above.

5.2 Pharmacokinetic properties

The elimination kinetics of streptokinase follows a biphasic course. A small proportion of the dose is bound to anti-streptokinase antibodies and metabolised with a half-life of 18 minutes while most of it forms a streptokinase-plasminogen activator complex and is biotransformed with a half-life of about 80 minutes.

Peak fibrinolytic activity is found in the blood about 20 minutes after dosing.

Like other proteins, streptokinase is metabolised proteolytically in the liver and eliminated via the kidneys. Animal data suggest that streptokinase may also be excreted unchanged in the bile.

5.3 Preclinical safety data

In an Ames Test on Streptokinase For Injection BP, no evidence of mutagenic potential was found. No other preclinical safety studies have been performed on Streptokinase For Injection BP.

6. Pharmaceutical particulars

6.1 List of excipients

Human albumin BP (20 %)
Gelatin BP
Sodium glutamate USP
Water for injection BP

6.2 Incompatibilities

No incompatibilities have been reported when Streptokinase For Injection BP is used as recommended. This medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

The shelf-life of unopened vials of Streptokinase For Injection BP is 3 years.

6.4 Special precautions for storage

Store below 25°C and do not freeze.

Do not store the reconstituted solution for more than 24 hours in a refrigerator at +2°C to +8°C.

6.5 Nature and contents of container

White colored poder filled in transparent glass vial with paper label and sealed with red colored flip off.

6.6 Special precautions for disposal and other handling

The contents should be dissolved in 4-5 ml of physiological saline or water for injection. The solution should be swirled gently to facilitate quick reconstitution, but care should be taken to avoid foaming.

Streptokinase For Injection BP may be given by intravenous infusion in 50-200 ml of physiological saline, 5% glucose solution, 5% fructose solution, or Ringer-lactate solution.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

8. Marketing authorisation number(s)

9. Date of first authorisation/renewal of the authorisation

10. Date of revision of the text

1500000 IU

FOR INJECTION BP

STREPTOKINASE

Label size : 50 x 29 x 70 mm

1 vial + 1 Ampoule of sterile water for injection 10 ml

STREPTOKINASE
FOR INJECTION BP

1500000 IU

Lyophilized for intravenous use

STERILE & PYROGEN FREE

Composition:
Each vial contains :
Streptokinase Concentrated Solution BP 1500000 IU

Dosage:
As directed by the Physician.

Storage:
Store below 25°C.
Do not freeze.

Direction for use:
Dissolve the content of the vial in 4-5 ml of Physiological Saline or Sterile Water for Injection.

The constituted solution should be used immediately after preparation.

THE PREPARATION IS ANTIGENIC

1 vial + 1 Ampoule of sterile water for injection 10 ml

STREPTOKINASE
FOR INJECTION BP
1500000 IU

Lyophilized for intravenous use

STERILE & PYROGEN FREE

Keep out of the reach of children.

Mfg. Lic. No.: 1804-B
Batch No. :
Mfg. Date :
Exp. Date :

Sterile water for injection 10ml
Batch No. } As per inside ampoule
Mfg. Date }
Exp. Date }

Manufactured by:
KWALITY PHARMACEUTICALS LTD.
Nag Kalan, Majitha Road,
Amritsar - INDIA

Expiry Date is 36 months from the Mfg. Date. For eg. Feb 2022 to Jan 2025

Check List for Labeling													Formulation No.:		
Work Order No. :	Version	Pharmacop.	Spell.	Compo.	Batch, Mfg. Exp.	Expiry as per Schedule 'P'	M.R.P.	Mfg. Lic.No./ Nutral Code	Packing	Category	Mfg. Name	Reg. No.	Check Order for strength, Volume & Packing	STORAGE
Matching all parameters between Box and Label														
Matching the parameter with label of leader brand														
Previous specimen artwork : REPEAT		Designed by : Lakhwinder Singh				Order Quantity		Party Name		Packing				
Checked by :		Approved by :		Authorized by:		Party Approval								
Production Incharge	QC Incharge	Q.A.		M.D.				Card Board used for carton : □ G/B □ W/B □ I.T.C. □ Pearl						

Label size : 55 x 20 mm

Composition:
Each vial contains :
Streptokinase Concentrated
Solution BP 1500000 IU

Dosage: As directed by the Physician.

Storage: Store below 25°C. Do not freeze.

Direction for use: Dissolve the content of the vial in 4-5 ml of Physiological Saline or Sterile Water for Injection.

The constituted solution should be used immediately after preparation.

THE PREPARATION IS ANTIGENIC

STREPTOKINASE
FOR INJECTION BP

1500000 UI

Lyophilized for intravenous use

STERILE & PYROGEN FREE

Keep out of the reach of children.

Mfg. Lic. No.: 1804-B

Batch No. :

Mfg. Date :

Exp. Date :

Manufactured by:
KWALITY PHARMACEUTICALS LTD.
Nag Kalan, Majitha Road, Amritsar - INDIA

Expiry Date is 36 months from the Mfg. Date. For eg. Feb 2022 to Jan 2025

Check List for Labeling													Formulation No.:		
Work Order No. :	Version	Pharmacop.	Spell.	Compo.	Batch, Mfg. Exp.	Expiry as per Schedule 'P'	M.R.P.	Mfg. Lic.No./ Nutral Code	Packing	Category	Mfg. Name	Reg. No.	Check Order for strength, Volume & Packing	STORAGE
Matching all parameters between Box and Label														
Matching the parameter with label of leader brand														
Previous specimen artwork : REPEAT			Designed by : Lakhwinder Singh				Order Quantity		Party Name		Packing			
Checked by :		Approved by :		Authorized by:		Party Approval								
Production Incharge	QC Incharge	Q.A.		M.D.			Card Board used for carton : □ G/B □ W/B □ I.T.C. □ Pearl							

100 x 172 mm

STREPTOKINASE
FOR INJECTION BP
1500000 IU

COMPOSITION:
Each vial contains:
Streptokinase concentrated solution BP ..... 1500000 IU

CATEGORY
Plasminogen activator; Fibrinolytic.

MOA
Streptokinase forms a complex with plasminogen which then converts plasminogen to plasmin. Plasmin breaks down clots as well as fibrinogen and other plasma proteins.
Absorption: Rapidly cleared from the circulation after IV use.
Excretion: Elimination half-life of streptokinase-activator complex: 23 minutes.

INDICATIONS & DOSAGE
Intravenous
Acute myocardial infarction
Adult: 1.5 million units as a single dose infused over 1 hr immediately after onset of symptoms.

Intravenous
Pulmonary thromboembolism ; Arteriovenous occlusions
Adult: Loading dose: 250,000 units infused over 30 min. Maintenance: 100,000 units/hr for 24-72 hr depending on the condition to be treated. For cerebral retinal thrombosis, 12 hr may be sufficient. Monitor treatment by maintaining thrombin clotting time at 2-4 times normal values.
Child: Loading dose: 2500-4000 units/kg over 30 min, followed by infusion of 500-1000 units/kg/hr, continued until reperfusion occurs, up to 3 days. Initial dose may be estimated by streptokinase resistance test. Monitor treatment by maintaining thrombin clotting time at 2-4 times normal values.

CONTRAINDICATIONS
Severe hypertension, recent stroke, cerebral neoplasm, recent history of peptic ulcer disease, ulcerative colitis, pancreatitis, subacute bacterial endocarditis, coagulation defects also due to liver or kidney disease, recent surgery, childbirth. Hypersensitivity, increased risk of cerebral bleeding, trauma. Pregnancy. Active internal bleeding, bleeding GI lesions.

ADVERSE EFFECTS
Fever, chills, back pain, abdominal pain, nausea, vomiting, arrhythmia, bruising, rash, pruritus, acute renal failure due to embolism and haemorrhage. Cerebral, peripheral and pulmonary embolism. Allergic reactions, liver enzyme abnormalities, hypotension.
Potentially Fatal: Haemorrhage; anaphylactic shock.

SPECIAL PRECAUTIONS&WARNINGS
Mitral stenosis associated with AF. Streptokinase treatment within last 12 mth, use after prolonged or traumatic CPR; diabetic retinopathy. Elderly.

DRUG INTERACTIONS
Antagonistic effects with antifibrinolytic agents e.g. aminocaproic acid.
Potentially Fatal: Anticoagulants, heparin, antiplatelet agents e.g. aspirin and dipyridamole affect platelet function increasing the risk of haemorrhage.

STORAGE
Store below 25°C. Do not freeze
Keep out of the reach of children.

PRESENTATION
one vial of 1 g powder + one 10 ml ampoule of sterile water for injection packed in a printed carton.

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