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 Authorization for EQUINE ANTI-RABIES IMMUNOGLOBULIN 1500IU/ML INJ 5ML

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

- **Equine Anti-Rabies Immunoglobulin 1500IU/5mL 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 over stocking 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 **04 January 2025**.

Table 1: Provincial estimates

Province	Six Months Estimate
Correctional Services	0
EC-MT	3000
EC-PE	1980
FS	576
GP	900
KZN	10000
LP	2500
MP	3500
NC	720
NW	500
SAMHS	0
WC	1500
Total	**25 176**

Yours sincerely

K Jamaloodien

KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 5/7/2024

SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

Section 21 Response Letter

7/4/2024 6:16 PM

Khadija Jamaloodien

National Department of Health
Dr AB Xuma Building
1112 Voortrekker Rd
Pretoria Townlands 351-JR
Pretoria
0187

Buhle.Mbongo@health.gov.za

Dear Khadija Jamaloodien,

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

Your application dated **7/4/2024 2:36 PM** refers

- ***A. STATUS: Approved***
- ***B. APPLICANT: Khadija Jamaloodien***
- ***C. IMPORTING COMPANY: Equity Pharmaceuticals (Pty) Ltd***
- ***D. PATIENT/(S):***
- ***E. UNREGISTERED MEDICINES:***

  GENERIC NAME: Equine Anti-Rabies Immunoglobulin

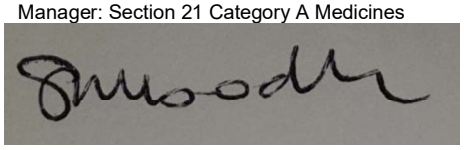
  TRADE NAME: Equirab 1500IU/5mL
- ***F. QUANTITY: Equine Anti-Rabies Immunoglobulin 1500IU/5ML INJ x 25000 vials***
- ***G. LETTER NUMBER: B-28720***

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

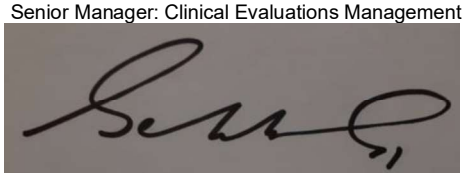
Comments:

Yours faithfully,

Dr S Munbodh
Manager: Section 21 Category A Medicines



T Sehloho
Senior Manager: Clinical Evaluations Management



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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 TO 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	S21RFQ135
QUOTE ENQUIRY DATE	20/06/2024	QUOTE CLOSING DATE			01/07/2024
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	**Human Immunoglobulin Anti-Rabies 150IU/mL INJ 2mL Intramuscular OR Equine Immunoglobulin Anti-Rabies 150IU/mL INJ 2mL Intramuscular**		
TRADE DESCRIPTION	Equirab 1500IU/5ml		
UNIT OF MEASURE	1's	PACK or BOX (*SIZE/ QUANTITY*)	1's
QUANTITY REQUIRED	**25 000 Vials**		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

COMPANY NAME	Equity Pharmaceuticals (Pty) Ltd			
SUPPLIER NUMBER	MAAA0007480			
SECURITY CODE				
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	**Jaco Schoeman**		
	PHONE	**012 345 1747**		

	MOBILE	*076 734 0080*	
	E-MAIL	**jacos@equitypharma.co.za**	
QUOTE DETAILS			
PRICE PER UNIT (INCL. VAT)	R148.12	TOTAL PRICE (INCL. DELIVERY & VAT)	R 3 703 000.00
VOLUMES AVAILABLE – 14DAYS	5 000 vials		
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 56DAYS	20 000 vials		
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	180 days		
NORMAL LEAD/DELIVERY TIME			
DEVIATION TO SPECIFICATION			
COMMENTS: Equine Rabies Immunoglobulin - 1 500IU/5ml (300IU/ml)			
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	**Ehrard van Zyl**		
CAPACITY	**Business Unit Manager: Specialist Medicine**		
SIGNATURE *(OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)*			
DATE	**01/07/2024**		
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
- Central Supplier Database Summary Report (CSD)
- 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 of the above is required to expedite the process in considering the quotation.

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

NB:

- 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.
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in pdf or word format only.
- All prices must please be submitted in two decimals.
- 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 documentation shall not be considered.
- Any submission with blurry relevant documents shall not be considered.
- The only electronic GMP Certificate considered is that from EUDRA.
- Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.

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

01/07/2024

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 # 20240701

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
	Equirab 1500IU/5ml vial	1's	1	R 128.80	R 148.12
			25 000	**R 3 220 000.00**	**R 3 703 000.00**
			25 000	**R 3 220 000.00**	**R 3 703 000.00**

Valid for 180 days

Employee Signature: _____

Date: 01 July 2024

Approved by: Ehrard van Zyl / Carel Bouwer

EQUITY
PHARMACEUTICALS

01/07/2024

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

National Department of Health

Directorate: Affordable Medicines

E-mail: Section21Quotes@health.gov.za

Attention: Ms Buhle Mbongo

Dear Ms Mbongo

Re: Request for quotation – Anti-Rabies Immunoglobulin – Section 21 Supply

Trust you are well. Please find below our quotation for *Anti-Rabies Immunoglobulin* supplied under section 21 terms.

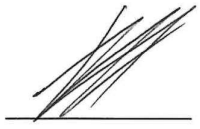
- Quantity: **25 000 vials**
- Delivery Time (Weeks): **6 weeks (5 000 vials within 14 days)**
- Price (Vat Inclusive): **R 148.12 per vial**
- Generic Name: **Anti-Rabies Immunoglobulin (Equine)**
- Trade Name: **Equirab 1500IU/5ml**
- Packaging: **1's (singles)**
- Specifications: **1500 IU/5ml**
- Shelf Life: **24 months**
- Package Insert: **Please find attached**
- Manufacturer: **Bharat Serums and Vaccines 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

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Rabies Antiserum I.P. - Equine

ईक्वीरॅब

Equirab

1500 IU / 5 ml

For I.M. / S.C. use

COMPOSITION :
Each vial contains :
Equine antirabies immunoglobulin fragments ….. not less than 300 I.U./ml
Water for Injection I.P. ..... q.s.
Preservative : Cresol I.P. ……..… NMT 0.25% v/v
Stabilizer : Glycine I.P., Excipient : Sodium Chloride I.P.

DESCRIPTION :
Equirab is a sterile non-pyrogenic solution for intramuscular administration, it contains antiviral substances obtained from the blood serum of healthy horses that has been immunized against rabies by vaccination, In addition it also contains the antimicrobial agent cresol.

THERAPEUTIC INDICATIONS :
Equirab provides passive immunization against rabies. For prevention of rabies in patients at risk of being exposed to rabies after contact with a rabid animal or a animal presumed to be rabid. **Equirab** itself does not constitute an antirabies treatment and should always be used in conjunction with rabies vaccine.

CONTRA-INDICATIONS :
Equirab should be used with extreme caution in subjects with a history of allergic symptoms or hypersensitivity to horse serum.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE :
Despite the high degree of purification of the serum, it is recommended to perform a skin test before administering **Equirab.** The skin test consists of an intradermal injection with a 1:10 dilution of **Equirab** (0.1ml) on the outside of the forearm so as to obtain an orange ring type appearance (3 mm diameter induration). An equivalent intradermal injection of physiological saline solution is used as control. The observations made 15 minutes after intradermal injection is considered to be positive if erythrema (>6mm), local oedema or a systemic reaction is observed and the control shows no such dermal reaction. Purified equine rabies immunoglobulin (the active Constituent of **Equirab** has been reported to be safe and affordable alternative to human rabies immunoglobulin. (Bulletin WHO 1989, 67(731-732). A positive test result is not a formal contra-indication for the use of serotherapy, but it should be considered as a warning. In such cases **Equirab** should be administered only after ensuring the facility to over come the anaphylactic shock. A negative test is not an absolute guarantee for the absence of an immediate allergic type reaction.

DRUG INTERACTIONS :
Rabies prevention after contamination risk requires simultaneous administration of antirabies immunoglobulin and vaccine. Anti rabies vaccine should be inoculated in a different part of the body, contra-laterally if possible. In this case intereference is minimised. The antiserum should not be administered in the same syringe as the vaccine.

PREGNANCY AND LACTATION :
The safety of **Equirab** when used during pregnancy has not been established in clinical trials in human beings. Considering the lethal risk associated with rabies, pregnancy is not a contra-indication to the administration of **Equirab** subsequent to exposure.

POSOLOGY :

First-aid treatment :

Prompt local treatment of bite wounds and scratches that may be contaminated with rabies virus is important, whatever the time elapsed since the contact. Recommended first-aid procedures are immediate thorough flushing and washing of the wound with soap and water, detergent or other substances of proven lethal effect on rabies virus. Rabies antiserum should be injected as soon as possible after exposure.

CATEGORY	TYPE OF CONTACT WITH A SUSPECT OR CONFIRMED RABID DOMESTIC OR WILD ANIMAL OR ANIMAL NOT AVAILABLE FOR OBSERVATION	RECOMMENDED TREATMENT
I.	Touching or feeding of animals, licks on intact skin.	None, if reliable case history is available.
II.	Nibbling of uncovered skin. Minor scratches or abrasions without bleeding. Licks on broken skin.	Administer vaccine immediately. Stop treatment if animal remains healthy throughout the observation period of 10 days or if the animal is killed humanely and found to be negative for rabies by appropriate laboratory techniques.
III.	Single or multiple transdermal bites or scratches. Contamination of mucous membrane with Saliva (i.e. licks)	Administer **Equirab** and Rabies vaccine immediately. Stop treatment if animal remains healthy throughout the observation period of 10 days or if the animal is killed humanely and found to be negative for rabies by appropriate laboratory techniques.

For prevention of rabies, combined immunoglobulin - vaccine treatment is recommended, although experience indicates that vaccine alone could be enough for minor exposure (Category II) The recommended dose is 40 I.U./Kg of body weight. If anatomically feasible, as much as possible of the dose should be infiltrated around the wounds. The remainder should be administered intramuscularly (into the gluteal region) in a single dose. The first dose of the vaccine should be inoculated at the same time as the immunoglobulin, but in different parts of the body. In no cases should the dosage of the rabies immunoglobulin be exceeded because immunoglobulin may partially suppress active production of antibodies. Children and adults receive the same dose of 40 I.U./Kg of body weight. When indicated, begin anti-tetanus treatment and administer antimicrobial drugs to control infections other than rabies.

UNDESIRABLE EFFECTS :

Immediate or delayed hypersensitive type reactions may be developed on administration of **Equirab.** The observed immediate reactions are anaphylactoid reactions with hypotension, dyspnea, urticaria. Delayed reactions consist of inflammatory reaction, fever, pruritis, rash or urticaria, adenopathy and arthralagia. Inform your doctor or pharmacist if you experience any undesirable effect.

PRESENTATION :

Vial containing 1200 IU (4 ml) and 1500 IU (5 ml).

STORAGE CONDITIONS :

Store at a temperature between 2°C and 8°C in a refrigerator.
Do not freeze.

Manufactured in India by :
BHARAT SERUMS AND VACCINES LIMITED
Plot No. K-27, Additional M.I.D.C.,
Ambernath (E) - 421 501

IN90017D3


Rabies
Antiserum I.P. - Equine
ईक्वीरॅब
Equirab 1500
1500 IU / 5 ml
For I.M. / S.C. use
Manufactured in India by :
BHARAT SERUMS
AND VACCINES LIMITED
Plot No. K-27, Additional M.I.D.C.,
Ambernath (E) - 421 501