



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 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 L-ASPARAGINASE 10 000IU INJECTION**

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

- **L-Asparaginase 10 000IU 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 7<sup>th</sup> 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.

**Section 21 Authorisation re L-Asparaginase 10 000IU INJ 16032026-1**

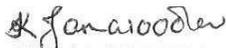
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, 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 **16 September 2026**.

**Table 1: Provincial estimates**

<b>Province</b>	<b>Six Months Estimate</b>
DCS	0
EC-MT	0
EC-PE	360
FS	0
GP	1 080
KZN	700
LP	120
MP	60
NC	20
NW	0
SAMHS	0
WC	400
<b>Total</b>	<b>2 740</b>

Yours sincerely



**KHADIJA JAMALOODIEN**  
**CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT**  
**DATE: 17/3/2026**

Department of Health • Lefapha la Pholo • Lefapha la Bophelo • uMnyango wezeMpilo • Muhasho wa Mutakalo • Departement van Gesondheid • Kgoro ya Maphelo • Ndzawulo ya Rihanyo • LiTiko la Thempilo • ISebe lezeMpilo • UmNyango WezamaPhilo

## Section 21 Outcome Letter

2026-03-16

Ms Buhle Mbongo

1112 Voortrekker Road

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Buhle Mbongo

### **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 **2026-03-16** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: Equity Pharmaceutical (Pty) Ltd**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 1500**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: L-Asparaginase for injection 10000 IU**
- G. QUANTITY: 3000 Packs (1 )**

S2100024434



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

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**H. LETTER NUMBER: S2100024434**

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:**

Yours faithfully,

Dr Shyamli Munbodh

Manager: Section 21 Category A Medicines

A rectangular box containing a handwritten signature in black ink. The signature appears to be 'M Moropa'.

Ms Mahlodi Moropa

Final Approver

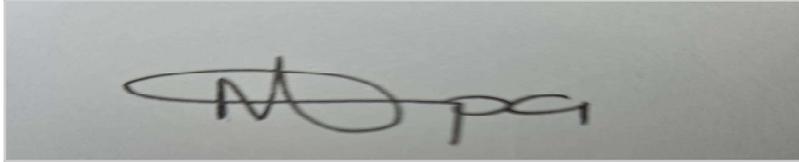
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S2100024434



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Building A, Loftus Park  
2nd Floor  
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Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA,  
0187 Tel (012) 395 8000, Fax (012) 395 8918

**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	S21RFQ170
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	<a href="mailto:Buhle.Mbongo@health.gov.za">Buhle.Mbongo@health.gov.za</a>				
PHONE No.	012 395 9539	FAX No.	N/A		

**PRODUCT INFORMATION**

DESCRIPTION PER MPC	L-ASPARAGINASE 10 000KU INJCTION				
TRADE DESCRIPTION	L-Asparaginase for injection 10 000IU (Lyophilized)				
UNIT OF MEASURE	1's	PACK or BOX (SIZE/ QUANTITY)	1's		
QUANTITY REQUIRED	1000 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	<a href="mailto:ehrdard@equitypharma.co.za">ehrdard@equitypharma.co.za</a>			
CONTACT PERSON 2	NAME	Hannes Strydom			
	PHONE	012 345 1747			
	MOBILE	082 616 1954			

E-MAIL		hannes@equitypharma.co.za	
<b><u>QUOTE DETAILS</u></b>			
PRICE PER VIAL (INCL. VAT)	R 328.90	TOTAL PRICE (INCL. DELIVERY & VAT)	R 328 900.00
*STOCK'S EXPIRY DATE(SHELF-LIFE)	36 months		
VOLUMES AVAILABLE – 7DAYS			
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS	1 000		
VOLUMES AVAILABLE - 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	180		
NORMAL LEAD/DELIVERY TIME	3 days		
<b><u>DEVIATION TO SPECIFICATION</u></b>			
<b>COMMENTS:</b>			
<b><u>DECLARATION BY SUPPLIER</u></b>			
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.			
<b>NAME</b>	Ehrard van Zyl		
<b>CAPACITY</b>	Business Unit Manager: Specialist Medicine		
<b>SIGNATURE</b> (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)			
<b>DATE</b>	27/02/2026		
<b><u>PROVINCIAL ESTIMATES</u></b>			
<b>Province</b>	<b>Six Months Estimate</b>		
DCS	0		
EC-MT	0		
EC-PE	0		
FS	0		
GP	0		
KZN	700		
LP	120		
MP	60		
NC	20		
NW	0		
SAMHS	0		
WC	0		

**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***

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**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***

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27/02/2026

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

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

## QUOTATION # 20260227/2

TO: National Department of Health

TEL : 012 395 9539

FAX :

Email : [Section21Quotes@health.gov.za](mailto:Section21Quotes@health.gov.za)

[www.clinigengroup.com](http://www.clinigengroup.com)  
[www.equitypharma.co.za](http://www.equitypharma.co.za)

CONTACT PERSON / PATIENT : Buhle Mbongo

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	TOTAL INCL
	L-Asparaginase for injection 10 000IU	1 x Vial	1	R 286.00	R 328.90
			1 000	R 286 000.00	R 328 900.00
			1 000	R 286 000.00	R 328 900.00

Valid for 180 days

Employee Signature: 

Date: 27/02/2026

Approved by: Ehrard van Zyl

27/02/2026

National Department of Health

Directorate: Affordable Medicines

E-mail: [Section21Quotes@health.gov.za](mailto:Section21Quotes@health.gov.za)

Attention: Ms Buhle Mbongo

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

+27 12 345 1747

+27 12 345 1412

[equity@equitypharma.co.za](mailto:equity@equitypharma.co.za)

[www.clinigengroup.com](http://www.clinigengroup.com)  
[www.equitypharma.co.za](http://www.equitypharma.co.za)

Dear Ms Mbongo

**Re: Request for quotation – L-Asparaginase 10 000IU – Section 21 Supply**

Trust you are well. Please find below our quotation for L-Asparaginase 10 000IU supplied under section 21 terms.

- Quantity: **1000 vials**
- Delivery Time (Weeks): **5 weeks**
- Price (Vat Inclusive): **R 328.90 incl. vat per vial**
- Generic Name: **L-Asparaginase**
- Trade Name: **L-Asparaginase for injection 10 000IU**
- Packaging: **1 vial**
- Specifications: **10 000IU / Vial**
- Shelf Life: **36 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



<b>Component : Carton</b>
<b>Dimension : 50 x 30 x 75 mm</b>
<b>Colour : CMYK</b>
<b>GSM : 320 gsm ITC CYBER XL</b>
<b>UV COATING</b>



Exp. :  
Mfg. :  
Batch :  
For Injection  
**L-ASPARAGINASE**

**10000 I.U. / Vial**

**L-ASPARAGINASE**  
For Injection

Contains the enzyme L-asparagine amidohydrolase, type EC-2, derived from *Escherichia Coli*

**Lyophilized**  
**For IM / IV use**

Single Use Vial  
Discard Unused Portion

**Composition:**  
Each vial contains:  
L-Asparaginase .... 10000 I.U.

Inactive ingredient:  
Mannitol ..... 80 mg  
No preservative

**Directions for Reconstitution:**  
See accompanying package insert.

**Dosage and administration:**  
As directed by the Oncologist.

Must reconstitute prior to administration. See accompanying package insert for complete dosage recommendations.

**Storage:**  
Store between 2°C to 8°C.  
Protect from light.  
Do not freeze.  
Keep out of the reach of children.

**10000 I.U. / Vial**

**L-ASPARAGINASE**  
For Injection

Contains the enzyme L-asparagine amidohydrolase, type EC-2, derived from *Escherichia Coli*

**Lyophilized**  
**For IM / IV use**

Single Use Vial  
Discard Unused Portion

If any foreign Particle is visible after dissolving the contents, Please do not use the solution.

**Caution:** May be a contact irritant. Avoid contact with skin, mucous membranes, or eyes. Do not inhale the dust or vapor. In case of contact, wash with copious amount of water for at least 15 minutes.

**WARNING:**  
Cytotoxic Agent. May cause severe reactions including sudden death.

Mfg. Lic. No.: BNZ/08/41

Manufactured by :  
**Kwality Pharmaceuticals Ltd.**  
1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Distt. Kangra, (H.P.) - 176201. INDIA

**Expiry Date is 36 months from the Mfg. Date. For eg. Feb/2019 to Jan/2022**

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	
<b>13682/1</b>	<b>ENGLISH</b>														
Matching all parameters between Box and Label															
Matching the parameter with label of leader brand															
Previous specimen artwork : <b>NEW</b>				Ramesh Kumar				Order Quantity		Party Name		Packing			
Checked by :		Approved by :		Authorized by :		Party Approval		2500 Vial		SD Pharma					
Production Incharge		QC Incharge		Q.A.		M.D.		Card Board used for carton :							
								<input type="checkbox"/> G/B <input type="checkbox"/> W/B <input type="checkbox"/> I.T.C. <input type="checkbox"/> Pearl							

**100 X 170 mm**

## L-ASPARAGINASE FOR INJECTION

Contains the enzyme L-asparagine amidohydrolase, type EC-2,  
derived from Escherichia Coli  
**10000 IU. / Vial**

### COMPOSITION:

Each vial contains:  
L-Asparaginase ..... 10000 IU.  
Inactive ingredient:  
Mannitol ..... 80 mg

No preservative

### PHARMACOLOGICAL CLASSIFICATION:

Cytostatic agents

### PHARMACOLOGICAL ACTION:

The tumour cells of acute leukaemia require exogenous Asparagine as an essential nutrient for their growth. Asparaginase is an enzyme which catalyses the hydrolysis of L-Asparagine to aspartic acid and ammonia, thus interfering with the metabolism of the malignant cells.

### INDICATIONS:

Lymphoblastic leukaemia (acute lymphatic leukaemia).

The different mechanism of action of L-Asparaginase and the fact that no cross resistance with other anti-leukaemic agents exists always justify a therapeutic trial when resistance against conventional cytostatics has developed.

### CONTRA-INDICATIONS:

Pregnancy.

Safety during lactation has not been established.

Patients with a history of hypersensitivity to Asparaginase.

### DOSAGE AND DIRECTIONS FOR USE:

The dry powder in the vial is dissolved, agitating slightly, with the added solvent i.e. 5% glucose or xyloitol or sterile physiological saline solution. The product is usually administered at doses of 200 to 800 IU/kg daily or on every other day. The dose should be adjusted according to the age and general condition of the patient.

According to clinical data the maximum tolerable dose is 2 000 IU/kg daily. Some authors recommend that the continuous dose after remission is 50 IU/kg daily. The duration of administration is usually 2 weeks. Treatment should be carried out as in-patient therapy.

L-Asparaginase is administered by slow intravenous injection or a rapid intravenous infusion (20 to 30 minutes) with physiological sodium chloride solution.

L-Asparaginase can be combined with differently acting cytostatics and/or corticosteroids. The stated dosage for Asparaginase can be maintained. In order to exclude the possibility of hypersensitivity the following tests should, as a rule, be performed prior to administration or before resuming treatment after an interruption. The detailed procedures of the tests should follow the routine ones in each laboratory.

a. Intracutaneous injection: 1 to 10 IU of Asparaginase in a volume of 0.1 ml. is to be injected intracutaneously on the palmar side of the forearm. The absence of abnormal signs should be confirmed 30 minutes to several hours after the injection.

b. Intravenous injection: Asparaginase, dissolved in a maximum of 250 mL of glucose solution, is administered by drop-infusion at doses of 50 - 1000 IU/kg depending on the age of the patient. The condition of the patient should be observed for one day and absence of any abnormal reaction confirmed.

### SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Shock symptoms may occur infrequently. If any symptoms such as clouding of consciousness, convulsions, blood pressure decrease, chills, fever or vomiting are observed, discontinue

administration immediately and adequate measures should be taken.

**Hypersensitivity:**

Hypersensitivity reactions such as rash may occur.

**Haematology:**

Since severe abnormality of coagulation (decrease of fibrinogen, prothrombin, plasminogen AT III and protein C etc) such as cerebral haemorrhage, cerebral infarction and pulmonary haemorrhage may occur, monitor the patient carefully by frequent laboratory examinations. \* Furthermore thrombocytopenia and anaemia may occur.

**Hepatic:**

Since hyperammonemia with disturbance of consciousness may occur, monitor the patient carefully by periodical examinations.

Furthermore, hepatic disorder and fatty liver may occur.

**Renal:**

Proteinuria, diuretic failure, azotemia and oedema may occur.

**Pancreatic:**

Since acute pancreatitis may occur and secretion dysfunction of pancreas (necrosis of Langerhans' islets) may induce diabetes, monitor the patients carefully. \*

**Brain:**

Death has been reported due to the wide range organic dysfunction of the brain.

**Gastrointestinal:**

Anorexia, nausea, vomiting and diarrhoea may occur.

**Psychoneurologic:**

Malaise, headache, and infrequently somnolence, anxiety, disturbance of consciousness and coma may occur.

**Other:**

Fever and glucose tolerance abnormality may occur.

- If any abnormal findings are observed, discontinue administration or adequate measures should be taken. Great care should be taken at the beginning of the administration. In view of the risk of sensitization once treatment has begun it should not be interrupted. If, however, an interruption should become unavoidable then treatment must be resumed with small doses (beginning with 10 IU/kg of body mass). If tolerance remains good the dose may be increased to the full daily dose in the course of 5 days.

It should be given cautiously to patients with impaired liver function. In patients with pancreatitis or a history of pancreatitis, acute haemorrhagic-pancreatitis has been reported following L-Asparaginase administration.

### KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS

**TREATMENT:**

Treatment is symptomatic and supportive.

### PRESENTATION:

Each vial containing 10000 IU packed in a printed carton.

### STORAGE:

Store between 2°C to 8°C. Protect from light. Do not freeze.

**KEEP OUT OF THE REACH OF CHILDREN.**

Manufactured by :

**Kwality Pharmaceuticals Ltd.**

I-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur,

Distt. Kangra, (H.P.) - 176201, INDIA