



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 Extension Authorization for ACICLOVIR EYE OINTMENT 3%

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

- **Aciclovir Eye Ointment 3%**

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.

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

Batho Pele - putting people first

Section 21 Authorisation re Aciclovir Eye Ointment 3% 02062025-1

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 **28 November 2025**.

Table 1: Provincial estimates

Province	Six Months Estimate	Actual Uptake
Correctional Services	0	0
EC-MT	300	1587
EC-PE	180	
FS	60	195
GP	600	648
KZN	500	0
LP	360	600
MP	1230	0
NC	200	200
NW	550	1200
SAMHS	36	0
WC	180	280
Total	4 196	4 710

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 21/6/2025

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

Section 21 Outcome Letter

2025-05-28

Ms Buhle Mbongo

National Department Of Health

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 **2025-05-27** 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: 10**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Aciclovir Eye Ointment BP 3% W/W**
- G. QUANTITY: 90 Packs**

H. LETTER NUMBER: S2100003953

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

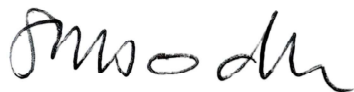
A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Dr S Munbodh

Manager: Section 21 Category A Medicines



T Sehloho

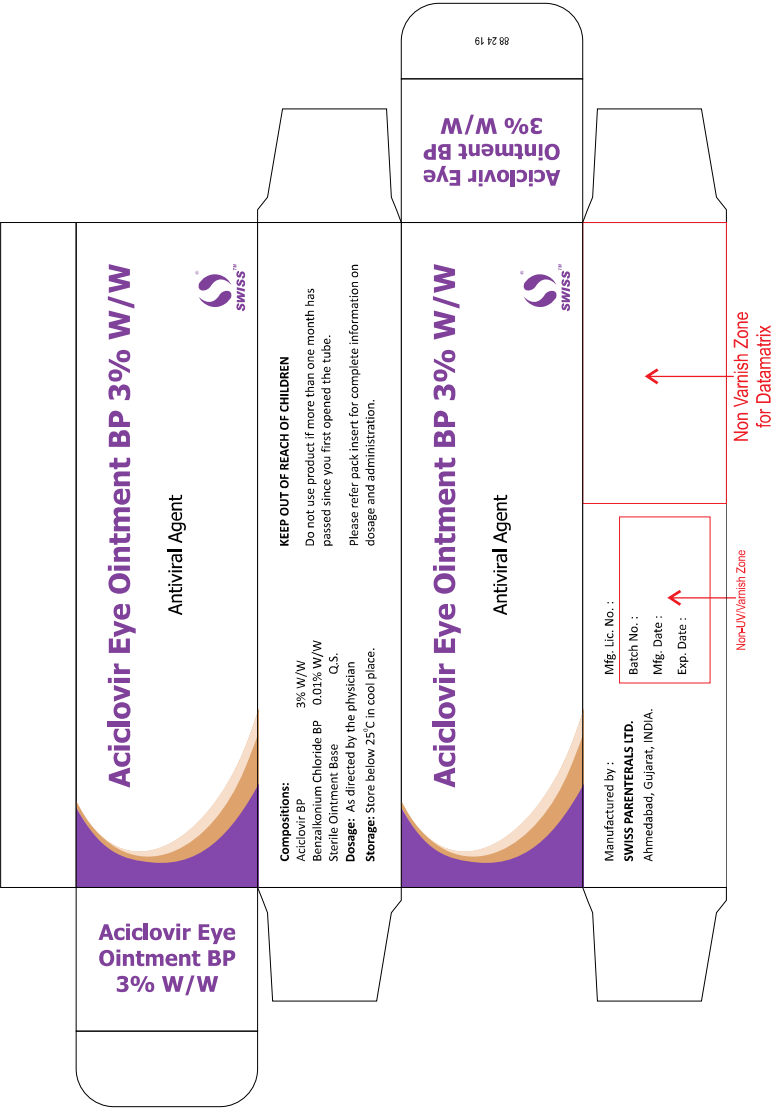
Senior Manager: Clinical Evaluations Management


S2100003953



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


A handwritten signature in black ink, appearing to read 'Gemma', is written across the page.





Aciclovir Eye Ointment BP 3% W/W

Antiviral Agent



Compositions:

Aciclovir BP	3% W/W
Benzalkonium Chloride BP	0.01% W/W
Sterile Ointment Base	Q.S.

Dosage: As directed by the physician

Storage: Store below 25°C in cool place.

KEEP OUT OF REACH OF CHILDREN


Do not use product if more than one month has passed since you first opened the tube.

Please refer pack insert for complete information on dosage and administration.

Mfg. Lic. No. :


Manufactured by :
SWISS PARENTERALS LTD.
Ahmedabad, Gujarat, INDIA.

Batch No. Month and Year of expiry on crimp.



Aciclovir Eye Ointment BP 3% W/W

Antiviral Agent



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SWISS PARENTERALS LTD.
Ahmedabad, Gujarat, INDIA.

Batch No. Month and Year of expiry on crimp.

Enlarge Size

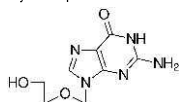
Aciclovir Eye Ointment BP 3% W/W

Composition:

Aciclovir BP	3 % W/W
Benzalkonium Chloride BP	0.01 % W/W
Sterile Ointment Base	Q.S

DESCRIPTION:

It contains Aciclovir. Chemical name of Aciclovir is 2-Amino-9-[(2 hydroxyethoxy)methyl]-1,9-dihydro-6H-purin-6-one.. Its molecular weight is 225.2 gm/mol. Its structure formula is



THERAPEUTIC CLASSIFICATION:

Antiviral agent

PHARMACODYNAMIC PROPERTIES:

Aciclovir is an antiviral agent which is highly active in vitro against herpes simplex (HSV) types I and II, but its toxicity to mammalian cells is low.

Aciclovir is phosphorylated to the active compound aciclovir triphosphate after entry into a herpes infected cell. The first step in this process requires the presence of the HSV coded thymidine kinase. Aciclovir triphosphate acts as an inhibitor of, and substrate for, herpes specified DNA polymerase, preventing further viral DNA synthesis without affecting normal cellular processes

PHARMACOKINETIC PROPERTIES:

Aciclovir is rapidly absorbed from the ophthalmic ointment through the corneal epithelium and superficial ocular tissues, achieving antiviral concentrations in the aqueous humor. It has not been possible by existing methods to detect aciclovir in the blood after topical application to the eye. However, trace quantities are detectable in the urine. These levels are not therapeutically significant.

INDICATION:

Treatment of herpes simplex keratitis.

RECOMMENDED DOSE:

Topical administration to the eye,

Adults: 1cm ribbon of ointment should be placed inside the lower conjunctival sac five times a day at approximately four hourly intervals, omitting the night time application. Treatment should continue for at least 3 days after healing is complete,

Children: As for adults

Use in the elderly: As for adults.

CONTRAINDICATION:

It is contra-indicated in patients with a known hypersensitivity to aciclovir or valaciclovir.

WARNINGS AND PRECAUTIONS:

Patients should be informed that transient mild stinging immediately following application may occur.

Patients should avoid wearing contact lenses when using it.

INTERACTION WITH OTHER MEDICINALS:

No clinically significant interactions have been identified

PREGNANCY AND LACTATION:

Pregnancy

A post-marketing aciclovir pregnancy registry has documented pregnancy outcomes in women exposed to any formulation of It. The registry findings have not shown an increase in the number of birth defects described amongst It exposed subjects compared with the general population, and any birth defects showed no uniqueness or consistent pattern to suggest a common cause.

Systemic administration of aciclovir in internationally accepted standard tests did not produce embryotoxic or teratogenic effects in rabbits, rats or mice. In a non-standard test in rats, foetal abnormalities were observed but only following such high subcutaneous doses that maternal toxicity was produced. The clinical relevance of these findings is uncertain.

The use of It Eye Ointment should be considered only when the potential benefits outweigh the possibility of unknown risks.

Breast-feeding

Limited human data show that the drug does pass into breast milk following systemic administration. However, the dosage received by the nursing infant following maternal use of It Eye Ointment would be insignificant.

Fertility

There is no information on the effect of aciclovir on human female fertility. In a study of 20 male patients with normal sperm count, oral aciclovir administered at doses of up to 1g per day for up to six months has been shown to have no clinically significant effect on sperm count, motility or morphology.

UNDESIRABLE EFFECTS:

Adverse reactions are listed below by MedDRA body system organ class and by frequency.

The frequency categories used are:

Very common	≥ 1/10
Common	≥ 1/100 and < 1/10
Uncommon	≥ 1/1,000 and <1/100
Rare	≥ 1/10,000 and <1/1,000
Very rare	<1/10,000

Clinical trial data have been used to assign frequency categories to adverse reactions observed during clinical trials with aciclovir 3% ophthalmic ointment. Due to the nature of the adverse events observed, it is not possible to determine which events were related to the administration of the drug and which were related to the disease. Spontaneous reporting data has been used as a basis for allocating frequency for those events observed post-marketing.

Immune system disorders:	
Very rare:	Immediate hypersensitivity reactions including angioedema and urticaria.
Eye disorders:	
Very common:	Superficial punctate keratopathy.

This did not necessitate an early termination of therapy and healed without apparent sequelae.

Common:	Transient mild stinging of the eye occurring immediately following application, conjunctivitis.
Rare:	Blepharitis.

Reporting of suspected adverse reactions.

OVERDOSE AND TREATMENT:

No untoward effects would be expected if the entire contents of the tube containing 135 mg of aciclovir were ingested orally. However, the accidental, repeated overdose of oral aciclovir, over several days, has resulted in gastrointestinal effects (nausea and vomiting) and neurological effects (headache and confusion). Aciclovir is dialysable by haemodialysis.

STORAGE CONDITION:

Store below 25°C in cool place.

KEEP OUT OF REACH OF CHILDREN

DOSAGE FORMS AND PACKING STYLE

Dosage form: Topical ointment

Packing Style: 5 gm Tube pack

Manufactured by:
SWISS PARANTERALS LTD.
Ahmedabad, Gujrat, India.



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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

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	S21RFQ126
QUOTE ENQUIRY DATE	28/02/2023	QUOTE CLOSING DATE	09/03/2023	
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	ACICLOVIR 3% EYE OINTMENT			
TRADE DESCRIPTION	Aciclovir Eye Ointment BP 3%			
UNIT OF MEASURE	1's	PACK or BOX (SIZE/ QUANTITY)	1's	
QUANTITY REQUIRED	5000			
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	0123451747	FAX	0123451412
	MOBILE	072 040 8511		
	E-MAIL	ehrd@equitypharma.co.za		
CONTACT PERSON 2	NAME	Jaco Schoeman		
	PHONE	0123451747		

	MOBILE	076 734 0080	
	E-MAIL	jacos@equitypharma.co.za	
<u>QUOTE DETAILS</u>			
PRICE PER UNIT (INCL. VAT)	R 49.45	TOTAL PRICE (INCL. DELIVERY & VAT)	R 247 250.00
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 56DAYS	5 000		
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD			
NORMAL LEAD/DELIVERY TIME			
<u>DEVIATION TO SPECIFICATION</u>			
COMMENTS:			
<u>DECLARATION BY SUPPLIER</u>			
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	Carel Bouwer		
CAPACITY	General Manager		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)			
DATE	09/03/2023		
Please submit quotations to Buhle.Mbongo@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.
- 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**

09/03/2023



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 # 20230309

TO: National Department of Health

TEL: 012 395 9539

FAX:

Email: Buhle.Mbongo@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
	Aciclovir Eye Ointment BP 3%	5g	1	R 43.00	R 49.45
			5 000	R 215 000.00	R 247 250.00
			5 000	R 215 000.00	R 247 250.00

Valid for 180 days

Employee Signature: _____

 P.P.

Date: 09/03/2023

Approved by: Ehrard van Zyl / Carel Bouwer

09/03/2023

National Department of Health

Directorate: Affordable Medicines

E-mail: Buhle.Mbongo@health.gov.za

Attention: Ms Buhle Mbongo

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equity@equitypharma.co.za

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Dear Ms Mbongo

Re: Request for quotation – Aciclovir Eye Ointment – Section 21 Supply

Trust you are well. Please find below our quotation for *Aciclovir Eye Ointment BP 3%* supplied under section 21 terms.

- | | |
|--------------------------|------------------------------|
| • Quantity: | 5 000 tubes |
| • Delivery Time (Weeks): | 7 weeks after approval |
| • Price (Vat Inclusive): | R 49.45 incl. vat per tube |
| • Generic Name: | Aciclovir Eye Ointment |
| • Trade Name: | Aciclovir Eye Ointment BP 3% |
| • Packaging: | 1 x 5g Tube |
| • Specifications: | 30mg/g |
| • Shelf Life: | 24 months |
| • Package Insert: | Attached |
| • Manufacturer: | Swiss Parenterals 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 / Carel Bouwer

09/03/2023

Equity Pharmaceuticals (Pty) Ltd.
1997/009942/07☎ +27 12 345 1747
☎ +27 12 345 1412
✉ equity@equitypharma.co.zawww.clinigengroup.com
www.equitypharma.co.za**QUOTATION # 20230309**

TO: National Department of Health

TEL: 012 395 9539

FAX:

Email: Buhle.Mbongo@health.gov.za

CONTACT PERSON / PATIENT: Buhle Mbongo

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Date: 09/03/2023

Approved by: Ehrard van Zyl / Carel Bouwer

09/03/2023

National Department of Health

Directorate: Affordable Medicines

E-mail: Buhle.Mbongo@health.gov.za

Attention: Ms Buhle Mbongo

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| • Specifications: | 30mg/g |
| • Shelf Life: | 24 months |
| • Package Insert: | Attached |
| • Manufacturer: | Swiss Parenterals 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 / Carel Bouwer