



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 C Mukaratirwa  
Cospharm Investments (Pty) Ltd  
2 Concourse Crescent  
Lonehill  
**Johannesburg**

Dear Mr Mukaratirwa

#### **Section 21 Authorization for ACICLOVIR 3% EYE OINTMENT 5G**

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

- **Aciclovir 3% Eye Ointment 5g**

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.
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.

**Section 21 Authorisation re Aciclovir 3% Eye Ointment 5g 04022026-1**

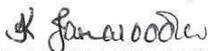
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent overstocking once the contracted supplier gets back 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 **30 July 2026**.

**Table 1: Provincial estimates**

<b>Province</b>	<b>Six Months Estimate</b>
<b>Correctional Services</b>	120
<b>EC-MT</b>	600
<b>EC-PE</b>	1 200
<b>FS</b>	100
<b>GP</b>	120
<b>KZN</b>	0
<b>LP</b>	860
<b>MP</b>	1 000
<b>NC</b>	200
<b>NW</b>	2 008
<b>SAMHS</b>	19
<b>WC</b>	350
<b>Total</b>	<b>6 577</b>

Yours sincerely



**KHADIJA JAMALOODIEN**  
**CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT**  
**DATE: 4/2/2026**

## Section 21 Outcome Letter

2026-01-30

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 **2026-01-30** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: COSPHARM INVESTMENTS (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 150**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Aciclovir 3 % w/w**
- G. QUANTITY: 3000 Packs (1 )**

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**H. LETTER NUMBER: S2100021132**

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

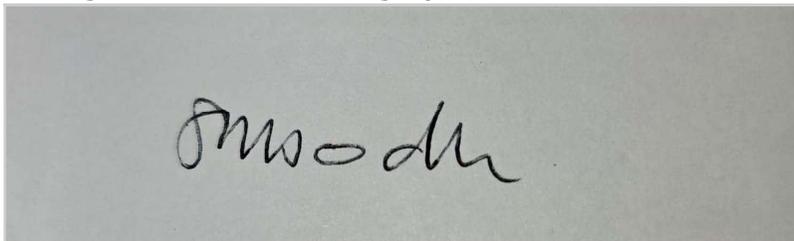
A progress report must be submitted once treatment is completed or on a reauthorization request

**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

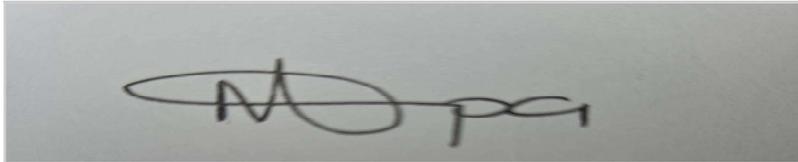
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S2100021132



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





# QUOTATION

Date: 2025/10/14

VAT Reg No.: 4640290963  
 Reg no: 2018/468705/07  
 Quote No. DOH003  
 Reference: BUHLE

**FROM: COSPHARM INVESTMENTS (PTY)LTD**  
 2 Concourse Crescent  
 Lonehill  
 Johannesburg  
**010 110 9348**

**TO: DEPARTMENT OF HEALTH**  
 Dr AB Xuma Building 1112, Voortrekker Road  
 Pretoria Townlands 315 JR  
 Pretoria, 0187  
**012 395 8000**

**BANKING DETAILS**

COSPHARM INVESTMENTS (PTY) LTD  
**FNB**  
 Account Number: 62850218241  
 Branch Code: 254605  
 Branch: Sandton City

Item Code	Item Description	Quantity	Disc %	Price excl	Price incl	Total (Incl)
ACICL100	ACICLOVIR 3% EYE OINTMENT	3000	0	R58,32	R 67,06	R 201 180,00

Validity Period: 90 Days  
 Lead Times: 4 weeks after receipt of a formal Purchase Order |  
 Country of origin: India  
 Manufacturer: Swiss Parentals Limited

<b>SubTotal (Excl)</b>	R	174 960,00
<b>VAT Total at 15%</b>		26 220,00
<b>Invoice Total ZAR</b>	R	201 180,00

Signature:  Name: S Ngomah

**Aciclovir Eye Ointment BP  
3% w/w**

# Aciclovir Eye Ointment BP 3% w/w

Antiviral Agent

5 g



**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.

**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.

# Aciclovir Eye Ointment BP 3% w/w

Antiviral Agent

5 g



Mfg. Lic. No. :

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



(00)000000000000000000000000  
(00)XXXXXXXXXXXXXXXXXXXX

Batch No. :

Mfg. Date :

Exp. Date :

**Aciclovir Eye  
Ointment BP  
3% w/w**

**5 g**

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Antiviral Agent



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**SWISS PARENTERALS LTD.**  
Ahmedabad, Gujarat, INDIA.

Expiry XX Months  
Batch No. & Mfg. Date  
See on the crimp

**5 g**

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See on the crimp

Enlarge

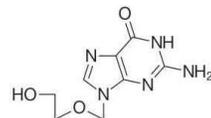
## Aciclovir Eye Ointment BP 3% w/w

### 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:	Blpharitis.

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.

**KEEP OUT OF REACH OF CHILDREN**

#### DOSAGE FORMS AND PACKING STYLE

**Dosage form:** Topical ointment

**Packing Style:** 5 gm Tube pack

Manufactured by:

**SWISS PARENTERALS LTD.**

Ahmedabad, Gujrat, India.