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 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 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 **28 February 2027**.

Table 1: Provincial estimates

Province	Six Months Estimate
Correctional Services	0
EC-MT	900
EC-PE	600
FS	80
GP	600
KZN	0
LP	1 000
MP	1 180
NC	200
NW	1 300
SAMHS	31
WC	30
Total	**5 921**

Yours sincerely

K Jamaloodien

KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 31/8/2026

S2100035996

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

Section 21 Outcome Letter

2026-08-31

Ms Khadija Jamaloodien

National Department Of Health

Pretoria

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 **2026-08-21** refers

A. STATUS: Approved

B. APPLICANT: Ms Khadija Jamaloodien

C. IMPORTING COMPANY: COSPHARM INVESTMENTS (PTY) LTD

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

E. UNREGISTERED MEDICINES: GENERIC NAME (INN / ACTIVE INGREDIENT): Aciclovir

F. TRADE NAME: Aciclovir Eye Ointment 3 % w/w

G. QUANTITY: 11340 Packs (1)

SAHPRA
South African
Health Products
Regulatory Authority

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

H. LETTER NUMBER: S2100035996

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

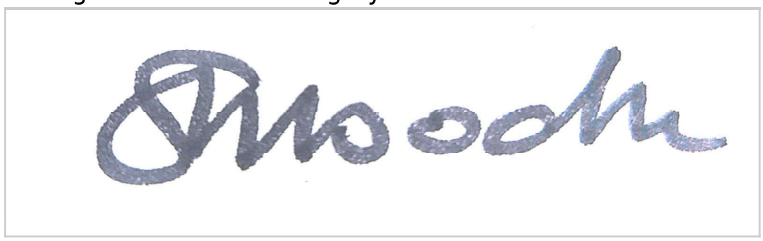
Comments:

No Data

Yours faithfully,

Shyamli Munbodh

Manager: Section 21 Category A Medicines



QUOTATION

Date 11/08/2026

VAT Reg No.:	4640290963
Reg no:	2018/468705/07
Quote No.	S21RFQ183/2026
Reference:	ACICLOVIR

FROM: COSPHARM INVESTMENTS (PTY)LTD	TO: DEPARTMENT OF HEALTH
2 Concourse Crescent Lonehill Johannesburg **010 110 9348**	Dr AB Xuma Building 1112, Voortrekker Road Preatoria 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 (Excl)
ACI100	ACICLOVIR 3% EYE OINTMENT 5G	11300	0	R55,80	R 65,65	R 630 540,00

Validity Period: 90 Days
Lead Times: 35 days after receipt of a formal Purchase Order
Country of origin: India
Manufacturer: Swiss Parentals LTD.

SubTotal (Excl)	**R**	**630 540,00**
VAT Total at 15%	R	111 305,00
Invoice Total ZAR	**R**	**741 845,00**

Name: Vibha Desai

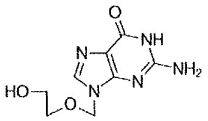
Signature:

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

24/02/26

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.
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.

Desai
24/02/26


Aciclovir Eye Ointment BP 3% w/w
Aciclovir Eye Ointment BP 3% w/w
5 g
Antiviral Agent
SWISS
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
5 g
Antiviral Agent
SWISS
Mfg. Lic. No. :
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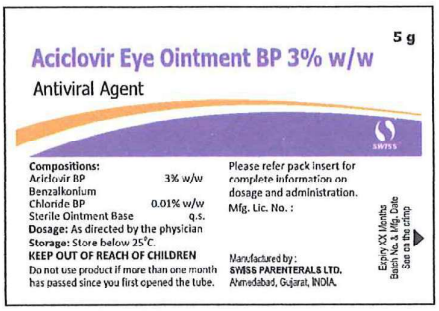
Ahmedabad, Gujarat, INDIA.
Batch No. :
Mfg. Date :
Exp. Date :

24/02/26



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

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Ahmedabad, Gujarat, INDIA.

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

Enlarge

Approved
24/02/26

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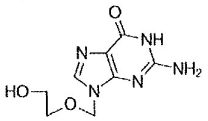

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