MICRO LABS LIMITED, BANGALORE, INDIA			
1	Product Name	Herperax Ointment	Colours Used
2	Strength	5% w/v	■ BLACK
3	Component	Leaflet	
4	Category	Export - Philippines	
5	Dimension	110 (L) x 160 (H) mm	
6	Artwork Code	EXG-ML01I-1821	
7	Pharma Code	387	
8	Reason for Change	New Artwork	

	Prepared by (DTP)	Checked by (PD)	Approved by			
			Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign	Kantharaju L.					
Date	14-03-2023					

110 mm

PHARMACODE READING DIRECTION

Front

110 mm

Back

160 mm

ACICLOVIR

HERPERAX

5 % Ointment

ANTIVIRAL

PRODUCT NAME:
Herperax

DOSAGE FORM AND STRENGTH:
ACICLOVIR 5%

PHARMACOLOGIC CATEGORY:
Antiviral

PRODUCT DESCRIPTION:
Aluminium tube (5g)

FORMULATION/COMPOSITION:
Each gram contains 0.05 g Aciclovir in an ointment base

INDICATIONS:
It is used mainly for the treatment of viral infections due lo herpes simplex virus (types 1 and 2) and varicella zoster (herpes and chickenpox).

DOSAGE AND MODE ROUTE OF ADMINISTRATION:
Treatment with Aciclovir (Herperax) ointment in herpes simplex infections of the skin including genital herpes and herpes labialis may be applied 5-6 times daily or every 34 hours for periods of5 to 10 days.

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S)
Patients with known hypersensitivity to Aciclovir

PRECAUTIONS AND WARNINGS:
Aciclovir (Herperax) 5% w/w ointment is not recommended for application to mucous membrane, such as mouth, eye or vagina, as it may be irritant. Particular care should be taken avoid accidental introduction into the eye.

PREGNANCY AND LACTATION:
There are no adequate & well controlled studies in pregnant women. II should be used during pregnancy only if potential benefit justifies the potential risk to the fetus. II is not known whether topically administered drug is excreted in breast milk. Caution should be exercised when Aciclovir (Herperax) ointment is administered to nursing women.

ADVERSE EFFECTS:
Transient burning or stinging may follow application of Aciclovir (Herperax) 5% w/w ointment in some patients. Mid drying and flaking of the skin, erythema and itching.

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STORAGE CONDITION:
Store at temperatures not exceeding 30°C
Keep out of reach of children

DOSAGE FORMS AND PACKAGING AVAILABLE:
Aluminium tube (5g) (Box of 1's)

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE):
Not Applicable

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
Marketing Authorization Holder
Brown & Burk Philippines Inc
U-501, 5/F., SEDCCO 1 Bldg., 120 Rada cor.,
Legaspi Sts., Legaspi Village, Makati City, Philippines

NAME AND ADDRESS OF MANUFACTURER:
MICRO LABS LIMITED
92, SIPCOT, HOSUR-635 126,
TAMIL NADU, INDIA

CAUTION STATEMENT:
FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

ADR REPORTING STATEMENT:
FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA:
www.fda.gov.ph

Seek medical attention immediately at the first sign of Adverse Drug Reaction.

REGISTRATION NUMBER:
DR No.: XY 30349

DATE OF FIRST AUTHORIZATION:
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DATE OF REVISION OF PACKAGE INSERT:
Jan. 2023

EXG-ML01I-1821

Size: 110 (L) x 160 (H) mm
Folded size: 110 mm x 21±1 mm
Carton size: 28 x 20 x 85 mm

14 (L) x 8 (H) mm

PHARMACODE READING DIRECTION

387

PHARMACODE READING DIRECTION