

Axcel<sup>®</sup>

**ACYCLOVIR**  
CREAM

5 Gm

Acyclovir / Aciclovir (micronised) 5% w/w

BATCH NO.:

**INDICATION:**

Treatment of herpes simplex virus infection of the skin including genital herpes and herpes labialis.

**DIRECTION FOR USE:**

For adults, children and geriatric: apply cream to the affected area 5 or 6 times daily for 5 to 10 days. Acyclovir cream should be applied to the lesions as early as possible after the start of an infection and particularly important to start treatment of recurrent episodes during the prodromal period or when the lesions first appear.

**Product Registration Holder and Manufacturer**  
KOTRA PHARMA (M) Sdn. Bhd.  
No. 1, 2 & 3, Jalan TTC 12, (90082-V)  
Cheng Industrial Estate,  
75000 Melaka, Malaysia.

**FOR EXTERNAL USE ONLY**  
**UNTUK KEGUNAAN LUAR SAHAJA**  
**KEEP OUT OF REACH OF CHILDREN**  
**JAUHI DARI KANAK-KANAK**

Keep container well closed.  
Store below 30°C. Protect from light.  
Please refer enclosed leaflet for more information.

Chlorocresol 0.1% w/w as preservative.  
219992587AZ CAM 419-09 HK-60340  
BRU08110153P MYN 1501AA2326

Controlled Medicine/  
414 Terkawal

EXP. DATE:

MFG. DATE:


REGN-11021

# Summary of Comments on Full page photo


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Page: 1


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 Number: 1 Author: RPD13 Subject: Highlight Date: 11/2/2021 4:24:11 PM


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 Author: RPD13 Subject: Sticky Note Date: 2/3/2021 3:29:44 PM  
To include manufacturing date on tube artwork.


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 Number: 2 Author: RPD13 Subject: Highlight Date: 11/2/2021 4:24:04 PM


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 Author: RPD13 Subject: Sticky Note Date: 2/3/2021 3:29:50 PM  
To update the registration number on the outer box with the new registration number (with suffix Z).


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 Number: 3 Author: RPD13 Subject: Highlight Date: 2/3/2021 3:29:54 PM  
To declare the product registration holder and manufacturer.


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 Number: 4 Author: RPD13 Subject: Highlight Date: 11/2/2021 4:23:46 PM


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 Author: RPD13 Subject: Sticky Note Date: 2/3/2021 3:31:46 PM  
Added in as per NPRA's remark during Correspondence 1.

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 Number: 5 Author: RPD13 Subject: Highlight Date: 11/2/2021 4:23:44 PM

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 Author: RPD13 Subject: Sticky Note Date: 2/3/2021 3:29:59 PM  
To remove the telephone number as it is not required based on labelling requirement (Appendix 9) in DRGD.