

Direct Healthcare Practitioners Communication (DHPC) Letter

Date: 02-04-2026

ACICLOVIR/ Acivision 3% 30MG/G EYE OINTMENT 5G. Absence of Arabic and English information on the outer packaging of one batch of Acivision 3% 30MG/G.

Subject:

Dear healthcare providers,

Alosool Medical Trading Company and Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

Expiry date	Batch No.	Product Name
31/05/2027	B0126	Acivision

Summary:

As per the quality report received by the pharmaceutical sector regarding this product, the following details were included:

- **The issue (Packaging defect)**
The outer packaging was included a quality defect in the information as it was written in a foreign language.
- **The affected batch**
The following batch number is affected as per SFDA notification: **B0126**
- **The corrective and preventive actions (CAPA's)**
As a corrective action for that defect, a letter to healthcare practitioners explaining the product's quality defect (the information on the outer packaging is not in Arabic or English), to this batch and including the English leaflet booklet.
- **The required actions from Direct Healthcare Practitioners (DHP's)**
It is recommended to use the enclosed leaflet in English to mitigate the defect caused by the lack of Arabic and English.

Further safety information:

- The enclosed leaflet should be carefully reviewed before dispensing the product.

Call for Reporting Any Quality Defects or Side Effects:

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to National Pharmacovigilance Centre (NPC- Saudi Food and Drug Authority (SFDA):

Website: <https://ade.sfda.gov.sa/>



E-mail: npc.drug@sfda.gov.sa

SFDA call center: 19999

Alosool Medical Trading company Contact point:

Name: Alhanouf Alabdulaziz In his capacity as: QPPV

E-mail: QPPV@omc-ksa.com

Mobile: 0535120254

For Medical Information enquiries, please contact:

Mobile: 0552040019

Email: Abdalkreem@omc-ksa.com

Annexes:

Acivision 3% 30MG/G Leaflet

This document is approved by The Executive Directorate of Pharmacovigilance at SFDA.

Best regards

Alhanouf Alabdulaziz

QPPV

1912327/01

Package leaflet: Information for the user

AciVision® 30 mg/g eye ointment

30.0 mg acyclovir/5 g, eye ointment

Active substance: Acyclovir

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine was prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What AciVision® 30 mg/g eye ointment is and what it is used for
2. What you need to know before you use AciVision® 30 mg/g eye ointment
3. How to use AciVision® 30 mg/g eye ointment
4. Possible side effects
5. How to store AciVision® 30 mg/g eye ointment
6. Contents of the pack and other information

1. WHAT ACIVISION® 30 mg/g EYE OINTMENT IS AND WHAT IT IS USED FOR

AciVision® 30 mg/g eye ointment is a medicine used to treat viral infections (antiviral). AciVision® 30 mg/g eye ointment is used for:
Herpes simplex virus-induced inflammation of the cornea of the eye.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ACIVISION® 30 mg/g EYE OINTMENT

AciVision® 30 mg/g eye ointment should not be used,

if you are hypersensitive (allergic) to acyclovir, valacyclovir, or any of the other ingredients of AciVision® 30 mg/g eye ointment.

Special care is required when using AciVision® 30 mg/g eye ointment

Immediately after use, a temporary slight stinging may occur. Avoid wearing contact lenses while using AciVision® 30 mg/g.

AciVision® 30 mg/g eye ointment and other medicines

Please inform your doctor or pharmacist if you are taking/using other medicines or have taken/used other medicines recently, even if these are non-prescription medicines.

What other medicines affect the action of AciVision® 30 mg/g eye ointment?

Interactions with other medicines are not yet known, but in the event of additional treatment with other eye drops/eye ointments, allow at least 15 minutes to pass between the use of different medicines. Eye ointments should be administered as a last resort.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking/using any medicines.

Use during pregnancy should be done after carefully weighing the possible risks against the likely benefits.

The available numerically limited data in humans indicate that acyclovir is excreted in human breast milk after systemic application. The dose which is reached by a breast-fed baby after use of acyclovir ointment or ophthalmic ointment in the mother is negligible, however.

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Driving and using machines

Eye ointments can lead to temporary impairment of vision. Particular caution is therefore indicated when driving or using machines.

3. HOW TO USE ACIVISION® 30 mg/g EYE OINTMENT

Use Acivision® 30 mg/g eye ointment exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The following information applies unless your doctor has prescribed Acivision® 30 mg/g eye ointment differently.

Please follow the instructions since otherwise Acivision® 30 mg/g eye ointment cannot work properly.

How much Acivision® 30 mg/g eye ointment should you use and how often should you use Acivision® 30 mg/g eye ointment?

Unless otherwise prescribed, you should apply an approximately 1 cm long strand of ointment into the lower conjunctival sac 5 times daily, every 4 hours.

How to use Acivision® 30 mg/g eye ointment

Pull down the lower eyelid to expose the conjunctival sac, then apply the strand of ointment. Close the eyelids and move the eyeball to distribute the ointment strand.

How long should you use AciVision® 30 mg/g eye ointment?

Your doctor will decide on how long your treatment will last.

You should continue the treatment for at least 3 days even after the conjunctivitis has been healed.

POSSIBLE SIDE EFFECTS

Like all medicines, Acivision® 30 mg/g eye ointment can cause side effects, although not everybody gets them.

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ to $< 1/100$)

Rare ($\geq 1/10,000$ and $< 1/1,000$)

Very rare ($< 1/10,000$)

For the classification of side effects into frequency categories, data from clinical trials with acyclovir 3% ophthalmic ointment were used. Due to the nature of the observed side effects, it is not possible to clearly determine which events are related to the administration of the medicine and which are associated with the disease. For the observed post-marketing side effects, spontaneous reports have been used as the basis for calculating the frequency.

Immune system disorders

Very rare: Acute hypersensitivity reaction including angioneurotic oedema and urticaria (hives).

Eye disorders

Very common: Superficial punctate keratopathy (superficial punctate corneal damage). This generally did not require ending the treatment prematurely and healed without visible consequences.

Common: Temporary light stinging or burning. Conjunctivitis (pinkeye). Rare: Blepharitis (blepharitis).

4. Reporting of suspected side effects

It is very important to report suspected side effects after authorization of the medicinal product. It allows continued monitoring of the benefit/risk ratio of the medicinal product. Health professionals are encouraged to report any suspected case of an adverse reaction to the

Federal Institute for Drugs and Medical Devices Department of Pharmacovigilance

Kurt-Georg-Kiesinger Allee 3 D-53175 Bonn

Website: www.bfarm.de

If you stop using AciVision® 30 mg/g eye ointment

Please strictly follow your doctor's dosage recommendations.

If you miss more than one application, please tell your doctor so that he or she may take additional measures, if appropriate.

If you want to interrupt the treatment because of side effects, please talk with your doctor so he or she may prescribe another medication, if appropriate.

5. HOW TO STORE ACIVISION® 30 mg/g EYE OINTMENT

Do not store above 25°C.

Keep medicines out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton and the tube crimp after "Use by". The expiry date refers to the last day of the month.

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Shelf life after opening the container:

Acivision® 30 mg/g eye ointment should not be used longer than one month after first opening the tube.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Acivision® 30 mg/g eye ointment contains

The active substance is: Acyclovir

1 g eye ointment contains 30 mg acyclovir.

Other ingredients: White petrolatum

What Acivision® 30 mg/g eye ointment looks like and the contents of the pack

Acivision® 30 mg/g ointment is a soft, white to off-white ointment Acivision® 30 mg/g ointment is available in packs with 4.5 g eye ointment.

Marketing Authorisation Holder

OmniVision GmbH

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82178 Puchheim

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This leaflet was last approved: 04/2014

Manufacturer

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1-56121 Pisa

Italy

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