Docusign Envelope ID: 5C09B455-20D8-44E1-A594-82AD02954978

Date: 23 December 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Fucithalmic 1% w/w Viscous Eye Drops/ Fusidic acid 1% w/w Viscous Eye Drops

Interim supply of Chinese stock to Mitigate supply disruption

Dear Healthcare Professional,

Summary: Fusidic acid 1% w/w Viscous Eye Drops - Amdipharm UK Limited

The MA Holder is the sole supplier of this product in UK.

To ensure continuity in supply, Amdipharm UK Limited has obtained approval from the Medicines and Healthcare products Regulatory Agency to supply *the repacked product for UK Market which was originally manufactured for the Chinese market. The reworked packs are with Tubes in Chinese language packed in UK registered Outer Carton along with the UK registered PIL in English language, which is identical in all respects to the Product registered in UK. The repacked product* is expected to be on the UK market starting from 31st Jan 2025.

Please see below the batch details:

Repacked Product batch details	
Repacked Batch Numbers & Quantity	C93945W10 - 3,999 packs C93945W10 - 3,999 packs C93945W10 - 1,505 packs C93945W10 - 1,499 packs Total reworked - 11,002 packs
Expiry Date	01/2026

Please note the following:

- This product is considered licensed in the UK
- The product manufactured for China i.e., Fucithalmic- Fusidic acid eye drops MA number HJ20171044 has the same formulation as the UK product**.**
- The product manufactured for China according to the same manufacturing process and quality controls as the UK product
- The product (Tube with Chinese text) manufactured for the Chinese Market is repacked for UK market with the UK approved Carton and PIL
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/or contact the company contact point (see below).
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Amdipharm UK Limited
Dashwood House/ 69 Old Broad Street/ London / EC2M 1QS / United Kingdom
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Company No 4606340

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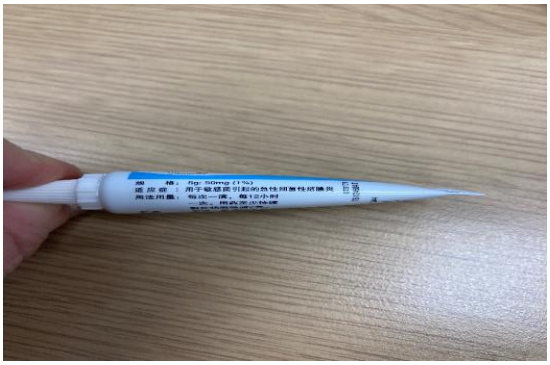
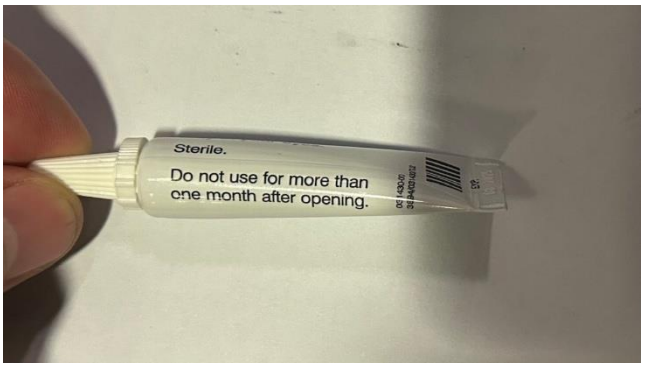
Images of imported product if labelling differs from standard UK product

Chinese pack	*Current registered UK Approved pack*
	
	

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.
Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.
When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contacts point

If you have any questions about this letter or wish more information about Fucithalmic 1% w/w Viscous Eye Drops, please contact Advanz Pharma Limited medical information at medicalinformation@advanzpharma.com or telephone +44(0) 0208 588 9131.

Signed by:
Subash Srinivasan
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Dr Subash Srinivasan
Senior Medical Director- Medical Affairs

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