DRUG SAFETY NOTICE

DRUG NAME/STRENGTH/FORM:

Carbomer-containing lubricating eye gels

PROBLEM

- UKHSA is investigating a *Burkholderia cenocepacia* outbreak identified across 12 different hospitals and the community.
 - Of 20 cases, 14 (70%) were critical care inpatients, two patients have cystic fibrosis (CF).
- Preliminary investigations have identified a potential association with carbomer containing lubricating eye gel, though investigations are ongoing, and these findings are not conclusive.

ADVICE / ALTERNATIVE

• UKHSA is working with NHS England and CF expert stakeholders to issue communications directly to CF patients, who will be directed to their CF Treatment Centres for further clinical advice.

ACTIONS

- As a precautionary measure until further information is available, it is recommended that carbomer-containing lubricating eye gels for dry eyes are avoided where possible in the following groups:
 - individuals with cystic fibrosis.
 - o critical care inpatients.
 - o severely immunocompromised inpatients; and
 - patients awaiting lung transplantation.
- Clinicians managing patients in these groups should consider ceasing use of carbomer containing eye gels for patient care until further information is available.
- For alternative products (including non-carbomer containing lubricating eye gels) see <u>Dry eye | Treatment summaries | BNF</u>.
- See below for details of a related recall of specific brands of carbomer eye gel.
 - Recall of AACARB eye gel, AACOMER eye gel and PUROPTICS eye gel: potential risk of infection, <u>DSI/2023/11</u>

N.B. SWB has not and does not stock these particular carbomer eye gels.

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Date :

Our Ref.:

Urgent Field Safety Notice

Indiana Ophthalmics LLP is issuing an urgent Field Safety notice to inform about the potential risk of microbial contamination in Carbomer eye Gel

Commercial name of the affected product: Carbomer Eye Gel (AACARB, AACOMER eye gel & PUROPTICS eye gel)

FSCA: 001/2023

Type of action: To withhold the distribution and recall the product from the market.

Date: 22/11/2023

Attention: Patients / Retailers / Healthcare Professionals / Distributors

Details on affected devices/ products:

Brand Name	Batch No.	Expiry Date	Pack Size	Product Photographs
AaCarb	3H07	07/2025	1 X 10 gm	Californie Gin Eye Gel
AaCarb	3H08	07/2025	1 X 10 gm	
AaCarb	3I02	08/2025	1 X 10 gm	
AaCarb	3103	08/2025	1 X 10 gm	Aucano Carbomer 0.2% Eye Gel
Aacomer 0.2% Eye Gel	3J23	09/2025	1 X 10 gm	Andreas (1.22%) Files Call Andreas (1.22%) Files Call
Aacomer 0.2% Eye Gel	3J24	09/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3K01	10/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3K02	10/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3H02	07/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3H03	07/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3H04	07/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3H05	07/2025	1 X 10 gm	
Aacomer 0.2% Eye Gel	3H06	07/2025	1 X 10 gm	
Puroptics Eye Gel	3H09	07/2025	1 X 10 gm	Active Calorier 0.2 (Dec Gel
Puroptics Eye Gel	3H10	07/2025	1 X 10 gm	
Puroptics Eye Gel	3H11	07/2025	1 X 10 gm	
Puroptics Eye Gel	3J07	09/2025	1 X 10 gm	
Puroptics Eye Gel	3J08	09/2025	1 X 10 gm	
Puroptics Eye Gel	3J09	09/2025	1 X 10 gm	

FOR FURTHER INFORMATION CONTACT

PHARMACY DEPARTMENT: CITY x5263; SANDWELL x3783

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