MHRA Device Safety Information

Reference: MDSI2311 **Issued:** 24 November 2023 **Review Date:** 24 November 2024

Specific brands of carbomer eye gel: recall of AACARB eye gel, AACOMER eye gel and PUROPTICS eye gel: potential risk of infection

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 24 November 2023. The original webpage can be accessed here.

Summary

Specific batches of carbomer gel are being recalled as a precaution due to possible microbiological contamination.

Action

Actions for healthcare professionals

- Follow the actions in the FSN including stopping supply or prescription of these specific affected gels named above to all patients/customers (supplied from August to November).
- Ask customers/patients to return any affected products.
- If appropriate, there is a poster attached to the FSN that can be used to draw attention to the recall.
- In addition, UKHSA has recommended that all carbomer containing eye gels (in other words, any carbomer containing lubricating eye gel product, not just those referred to in the FSN) are avoided where possible in individuals with cystic fibrosis, patients being cared for in critical care settings (e.g. intensive care), or who are severely immunocompromised and in hospital, and for patients awaiting lung transplantation.
- Alternative products (including non-carbomer containing lubricating eye gels) are available, see Dry eye, Treatment summaries, from the BNF.
- Healthcare professionals should report incidents to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system

For information: clinicians should be aware of the actions MHRA has recommended to patients

- Stop using affected batches of the products listed in the FSN and return the product to the place of sale.
- Contact a healthcare professional for advice if required.
- If you are worried about your health in relation to this recall, contact a healthcare professional. Tell them you have been using a recalled eye gel.
- If you are an individual with cystic fibrosis and have been using carbomer containing lubricating eye gel, please stop using it and contact your cystic fibrosis clinical treatment centre for advice.
- If you are an individual awaiting a lung transplant and have been using carbomer containing lubricating eye gel, please stop using it and contact your chest physician or GP for advice.

Equipment details

Device Name:	AACARB eye gel, AACOMER eye gel and PUROPTICS eye gel
Distributed after:	August 2023
Product code:	CB048G1H
Affected lot numbers:	3H02, 3H03, 3H04, 3H05, 3H06, 3H07, 3H08, 3H09, 3H10, 3H11, 3I02. 3I03, 3J07, 3J08, 3J09, 3J23, 3J24, 3K01, 3K02. See full details in table in FSN.
Manufactured by:	Indiana Ophthalmics LLP.

AACARB is labelled with distributor name:	Trion Pharma
AACOMER is labelled with distributor name	Essential-Healthcare
PUROPTICS is labelled with distributor name:	Biromantic Pharma

Background

There is a potential risk of contamination of specific brands of carbomer eye gels with a type of bacteria called Burkholderia cenocepacia. An investigation by UKHSA has identified a potential association with these specific eye gels. Investigation and testing are still ongoing and these eye gels are being recalled as a precaution.

UKHSA considers the risk to the general public from Burkholderia cenocepacia to be very low, but some patient groups (such as individuals with cystic fibrosis) are at higher risk of adverse effects. As a precautionary measure until further information is available, UKHSA has recommended that **all** carbomer containing eye gels are avoided where possible in individuals with cystic fibrosis; patients being cared for in critical care settings (e.g. intensive care), or who are severely immunocompromised and in hospital, and for patients awaiting lung transplantation. Non-carbomer containing lubricating products are available, see Dry eye, Treatment summaries, from the BNF.

These eye gels are medical devices. The manufacturer of these devices has issued a Field Safety Notice (FSN) to advise all customers of the required actions.

Suggested onward distribution

Critical care
Emergency Department
General Medical Practitioners
Health Centres
Health & Safety
Hospices
Infection Control Staff
Operating Departments
Operating Department Practitioners
Ophthalmology
Optometrists
Risk Management
Pharmacy
Supplies/Procurement

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

Report an incident: Information on how to report an adverse incident

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service https://www.nss.nhs.scot/