National Patient Safety Alert

UK Health Security Agency

Potential contamination of some carbomer-containing lubricating eye products with *Burkholderia cenocepacia* – measures to reduce patient risk

Date of issue:	07/12/2023	Reference no:	NatPSA/2023/015/UKHSA

This alert is for action by: Acute trusts, private providers/independent treatment centres providing NHS care, ambulance trusts, mental health trusts, community trusts, general practice and hospital and community pharmacy, and other health and care providers using/providing carbomer-containing lubricating eye products.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards).

Explanation of identified safety issue:

UKHSA is investigating an outbreak of *Burkholderia cenocepacia* involving individuals across the UK. This is an emerging issue and, following testing, *B. cenocepacia* was recovered from some lubricating carbomer eye products.

A Field Safety Notice (FSN) NOTE A issued on 24 November 2023 recalled batches of three carbomer-containing lubricating eye gels. The Medicines and Healthcare products Regulatory Agency (MHRA) issued accompanying Device Safety Information (DSI) NOTE B with advice to health professionals, patients and customers. UKHSA issued Briefing Notes on 21 and 28 November 2023, containing recommendations which are updated in this alert.

UKHSA has recovered *B. cenocepacia* from a small number of carbomer-containing eye products including, but not exclusively, from recalled products; where typing has occurred one product contained the outbreak strain.

There are currently 32 confirmed cases in England and Scotland, identified from 16 hospitals and the community. Specimen dates are between January and November 2023 (majority October to November 2023). Twenty-three of 32 (72%) were critical care inpatients, 2 (6%) had cystic fibrosis, and 3 (9%) were children aged under 3 months. These were a combination of colonisations and infections.

B. cenocepacia is a species of the *Burkholderia cepacia* complex (Bcc) found in natural environments. Bcc are opportunistic pathogens, rarely causing infection in healthy individuals but can cause severe infections in some groups, including those with cystic fibrosis (CF), immunocompromised, and critical care inpatients.

Health professionals should be aware that some carbomer-containing eye gels may not be sterile. As a precautionary measure, until further information is available, UKHSA is making recommendations to protect patients including those most at risk of significant health consequences [e.g., invasive infection and death] from *B. cenocepacia*. Other non-carbomer-containing products are available.

Actions required

Actions to be completed by 17 December 2023

1. Ensure that products specified in the FSN are removed from clinical settings immediately and procurement of these is ceased. Quarantine all remaining stock and contact the relevant supplier/ distributor to arrange return.

2. Health professionals should follow actions specified in the DSI NOTE B including on reporting of related incidents (this will be updated if/as new information arises).

3. As a precautionary measure, while further testing is conducted, avoid use of all carbomer-containing lubricating eye products for patients in the following groups NOTE C:
   - individuals with cystic fibrosis
   - patients being cared for in critical care settings (e.g., adult, paediatric and neonatal ICU)
   - severely immunocompromised
   - patients awaiting lung transplantation.

   Where an alternative non carbomer-containing product is not available or not suitable, apply clinical risk assessment as appropriate NOTE D.

4. NHS Trusts and independent sector laboratories are requested to submit any isolate from a new infection with *Burkholderia cepacia* complex, including any new isolations from cystic fibrosis patients to the UKHSA AMRHAI reference laboratory (details provided below).

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: hcaiamr.ios@ukhsa.gov.uk

Additional information:

NOTES: Information on product recall

A. Indiana Ophthalmics LLP issued a Field Safety Notice to withdraw and recall 19 batches of three carbomer containing lubricating eye gel products. These recalled products are normally available over the counter, online and are prescribed. Details regarding the product recall including instructions on contacting Indiana Ophthalmics and the concerned distributors for the return of products are provided in the FSN.

B. MHRA has provided information, including product codes, and precautionary safety advice on GOV.UK via a Device Safety Information notice (DSI/2023/11). The DSI will be updated if/as new pertinent information arises.

Certain batches of the following product brands are subject to recall at present (see FSN for details):

- AACARB eye gel
- AACOMER 0.2% eye gel
- PUROPTICS eye gel.

C. UKHSA has issued two Briefing Notes (BN 2023/045 on 21 November 2023 and BN 2023/047 on 28 November 2023) providing recommendations on the use of carbomer-containing lubricating eye products for clinicians managing at-risk clinical groups. These recommendations included the above with the exception that we are now extending recommendations to cover all severely immunocompromised patients (previously referred to inpatients). UKHSA has also issued advice to CF patients which has been disseminated via NHS CF treatment centres, and to CF clinical networks.

D. Clinicians may wish to extend these measures outside of these categories to individuals who they consider to be very high risk of invasive infection, on a prospective basis, based on their clinical judgement.

Further information on *Burkholderia cenocepacia*

Burkholderia cenocepacia can cause severe infections in individuals with CF, people who are immunocompromised or on intensive care. Presence of *B. cenocepacia* can be a contraindication to lung transplantation in some circumstances. Bcc are naturally resistant to a range of biocides and have been associated with contamination of medicinal and hygiene products used in health and care settings.

Instructions for laboratories regarding submission of isolates

Laboratories are asked to be extra vigilant for this organism as it is not a notifiable causative agent.

Please submit isolates to the AMRHAI reference laboratory using the Healthcare pathogens request form H1 (multiple isolates) or H2 (single isolates) available at AMRHAI reference unit: reference and diagnostic services.

Stakeholder engagement

The following stakeholders have been engaged in the incident management and consulted in the drafting of this alert: NHS England, Department of Health and Social Care, Medicines & Healthcare products Regulatory Agency, Royal College of Ophthalmologists, Antimicrobial Resistance and Healthcare Associated Infection Scotland (ARHAI) Scotland, Public Health Wales, Public Health Agency, Northern Ireland, NHS Supply Chain.

Infection-related hazards	England*
Chemical-related hazards	England & Wales*
Radiation-related hazards	The whole of the UK

**Devolved nations may choose to endorse, disseminate, or adapt them for use.*

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts.