



Medicines & Healthcare products Regulatory Agency

Title

Specific brands of carbomer eye gel: recall of AACARB eye gel, AACOMER eye gel and PUROPTICS eye gel: potential risk of infection, DSI/2023/11.

Summary

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

Devices Details

Device Name: AACARB eye gel, AACOMER eye gel and PUROPTICS eye gel

Distributed After: August 2023

Product code: CB048G1H

Affected lot numbers/serial 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: Biovantic Pharma.

Explanation of identified safety issue

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.

Actions

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:
 - in England and Wales to the [Yellow Card scheme](#) or via the Yellow Card app
 - in Scotland to [Incident Reporting & Investigation Centre \(IRIC\)](#) and their local incident recording system
 - in Northern Ireland to the [Northern Ireland Adverse Incident Centre](#) and their local incident recording system

Actions for all patients/customers

- 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.

Actions for distributors

- Send customers copies of the FSN and poster.

Stakeholder engagement

UKHSA, Royal College of Ophthalmologists, DHSC, NHS England, Scottish Government, Welsh Government and Northern Ireland

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