

0.9% Sodium Chloride Solutions for Irrigation, Inhalation, and Eyewash: recall from manufacturer Legacy Remedies Private Ltd: potential risk of infection

Batches of Legacy Remedies Pvt Ltd irrigation, inhalation and eye wash saline products manufactured between April and November 2023 are being recalled due to potential microbiological contamination.

Devices Details

Device Name: Sodium Chloride Irrigation Solution 0.9% w/v, Sodium Chloride Eye Wash Solution 0.9% w/v and Sodium Chloride Inhalation Solution 0.9% w/v

Affected lot numbers/serial numbers: All products manufactured between April and November 2023. Refer to Attachment 2 in the [Field Safety Notice \(FSN\)](#) for affected batches.

Manufactured by: Legacy Remedies Pvt Ltd.

Explanation of identified safety issue

Potential contamination with *Ralstonia pickettii* (*R. pickettii*) has been identified in 0.9% sodium chloride solutions used for irrigation, inhalation and eyewash manufactured by Legacy Remedies Pvt Ltd.

R. pickettii is a type of environmental waterborne bacteria that has the potential to contaminate healthcare products. The bacterium has the ability to create and sustain biofilms, which may pose challenges in effectively removing them from indwelling lines and devices utilised for saline solution administration. In individuals with compromised immune systems, *R. pickettii* can lead to opportunistic infections. It is important to note that cases of *R. pickettii* in the UK are rare.

The UK Health Security Agency (UKHSA) is currently investigating a cluster of *R. pickettii* cases. There have also been similar cases reported in Australia. Analysis of the UK and Australian *R. pickettii* samples show that they are very closely related which suggests they share a common source of infection. The UK and Australian cases have been linked to contaminated saline products that were utilised for irrigation and inhalation purposes in healthcare and care facilities.

Legacy Remedies Pvt Ltd has identified through testing that seven batches of 0.9% sodium chloride irrigation solution have not met sterility standards. These batches were removed and disposed of before being sold in the UK. However, following investigation and as a precautionary measure, the company has additionally recalled all 0.9% sodium

chloride solutions intended for irrigation, inhalation, and eyewash manufactured between April and November 2023 which could potentially also be contaminated.

As of 3 April 2024, three cases of *R. pickettii* have been confirmed in the UK, and a small number of other cases are under investigation. The confirmed infections occurred in individuals who have multiple underlying health conditions and compromised immune systems. *R. pickettii* was isolated in blood samples and was associated with clinically significant infections in each case. All confirmed cases received treatment and recovered.

These sodium chloride solutions are categorized as medical devices. The products may be sold individually or as components of equipment kits, which vary from aseptic clinical equipment packs to first aid kits intended for non-clinical settings. The manufacturer of these devices has released a [FSN](#) to notify all customers of the necessary steps to be taken. The overall risk to the general public is very low.

Actions

Actions for healthcare professionals and providers

- Review your inventory of 0.9% sodium chloride solutions intended for irrigation, inhalation and eyewash, and determine if any of the batch numbers listed in the [FSN](#) are present in your stock.
- Check any clinical equipment packs or first aid kits that might contain any of the 0.9% sodium chloride solutions listed in the [FSN](#) and determine if any of the batch numbers listed in the [FSN](#) are present in these packs.
- Immediately stop use, quarantine and stop supply of any identified product(s).
- Where possible, contact any customers who have received or may have received the affected product(s) and ask them not to use the product(s) and to return them to the original place of purchase.
- Follow the actions set out in the [FSN](#).
- There are specific reporting arrangements for healthcare professionals to follow in each region. 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
- Alternative sodium chloride 0.9% solution products are readily available for use in irrigation, inhalation and eye wash. Suppliers of these products have been contacted and have confirmed there is adequate supply in the market to support the recall of affected Legacy batches.

Actions for patients/customers

- If you use any 0.9% sodium chloride solution intended for irrigation, inhalation, or eyewash, check if you have any of the affected batches listed in the [FSN](#).
- Immediately discontinue the use of any identified batches of products listed in the [FSN](#) and promptly return them to the original place of purchase.
- If you have concerns regarding your health in connection with this recall, contact a healthcare professional for guidance. Tell them that you have been using a product that has been recalled due to potential contamination with *R. pickettii*.

Actions for distributors

- Send customers copies of the [FSN](#).
- Review your inventory of 0.9% sodium chloride solutions and determine if any of the batch numbers listed in the [FSN](#) are present in your stock.
- Immediately quarantine and stop supply of any identified product(s).
- Follow the actions set out in the [FSN](#).

Stakeholder engagement

UK Health Security Agency (UKHSA)

NHS Supply Chain

Department of Health and Social Care (DHSC)

NHS England

NHS Scotland

NHS Wales

NHS Northern Ireland

Mandatory

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