

Medical Device Alert

MEDICAL DEVICE VOLUNTARY RECALL

Date: 19th April 2024

Medicines Authority Ref No: MDA 01-04/24

Laboratoire de la Mer, a Perrigo Company is recalling one batch of **PHYSIOMER BABY UNIDOSE** in Malta

Laboratoire de la Mer, a Perrigo company, in agreement with the Malta Medicines Authority is voluntarily recalling 1 batch of **Physiomer Baby Unidose** in Malta at wholesaler, pharmacy and patient level. Physiomer Baby Unidose is used for nasal washing and eyelid cleaning of infants from birth.

Laboratoire de la Mer commitment to ensuring the safety of the product led us to take immediate action to address a potential contamination issue identified during the sterile manufacturing process. No contamination has been identified in the product itself and no incident related to this voluntary recall has been reported. To protect patient safety Laboratoire de la Mer is voluntarily recalling specific batch **G239469** from wholesalers, pharmacies and patients in Malta.

The recalled Physiomer Baby Unidose is identified by the batch number **G239469**, expiry date: 03 / 2027. The batch number is printed on Physiomer Baby Unidose as indicated in Figure 2A and B.



Figure 1. Outer package of Physiomer Baby Unidose



Figure 2A. Batch number is shown on this side of the box

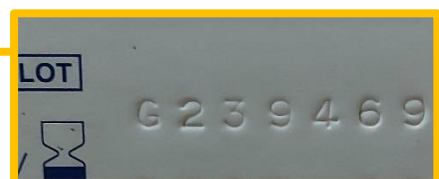


Figure 2B. Batch number

Advice to patients or carers in possession of Physiomer Baby Unidose with the batch number G239469:

Return the product with batch number **G239469** to your pharmacy.

You will be refunded by the pharmacy.

The pharmacist may advise you on an alternative product.

Report any safety concerns to Pharmasud Limited on the contact email address shown below or to Malta Medicines Authority Medical Devices Directorate on mdvigilance.medicinesauthority@gov.mt and complete the Public Incident Report Form available on: <https://medicinesauthority.gov.mt/mdforms>

There is no concern if you are in possession of Physiomer Baby Unidose with batch number **NOT** mentioned above.

Further information

Local Contact point

Pharmasud Ltd

Contact point: Chris Vella

P: +356 2137 6436 M: +356 9993 8772

Email address:

sales@pharmasud.com

Malta Medicines Authority:

Medical Devices and Pharmaceutical Collaboration Directorate

Website: [Medicines Authority \(gov.mt\)](http://Medicines Authority (gov.mt))

Email address: mdvigilance.medicinesauthority@gov.mt

Contact Numbers: 23439164; 23439259; 23439261