



Notice no. 20

19.04.2024

Twissija dwar Taghmir Mediku RECALL VOLONTARJU TA' TAGHMIR MEDIKU

Data: 19th April 2024

Medicines Authority Ref No: MDA 01-04/24

Laboratoire de la Mer, kumpanija ta' Perrigo, qiegħda tiġbor lura lott ta' *PHYSIOMER BABY UNIDOSE* f'Malta

Laboratoire de la Mer, kumpanija ta' Perrigo, bi ftehim mal-Awtorità dwar il-Medicini, qiegħda tiġbor lura volontarjament lott wieħed ta' **Physiomer Baby Unidose (Figure 1)** f'Malta mingħand bejjiegħa bl-ingrossa, spiżeriji u pazjenti. Physiomer Baby Unidose huwa użat għall-ħasil tal-immieher u t-tindif tal-eyelid tat-tfal żgħar sa mit-twelid.

Biex jassiguraw is-sigurtà tal-prodott, Laboratoire de la Mer waslu biex jieħdu azzjoni immedjata biex jindirizzaw xi possibbiltà ta' kontaminazzjoni li setgħet ġrat waqt il-proċess sterili tal-manifattura.

L-ebda kontaminazzjoni ma ġiet identifikata fil-prodott innifsu u l-ebda inċident ma ġie rrapportat konness ma' din ir-recall volotarja. Biex niproteġu s-sigurtà tal-pazjenti Laboratoire de la Mer qiegħda volontarjament tiġbor lura l-lott specifiku **G239469** mingħand il-bejjiegħa bl-ingrossa, spiżeriji u pazjenti f'Malta.

Il-Physiomer Baby Unidose li qed jingabar lura huwa identifikat bil-batch number **G239469**, expiry date: 03 / 2027. Il-batch number hu stampat fuq Physiomer Baby Unidose kif indikat fil-Figuri 2A u B.



Figure 1. Il-pakkett ta' Physiomer Baby Unidose



PRESS NOTICE



Figure 2A. Batch number fejn jidher fuq il-pakkett

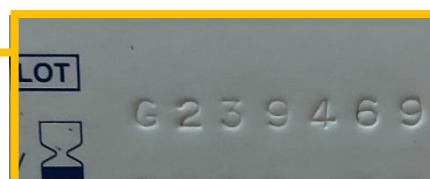


Figure 2B. Batch number

Rakkomandazzjoni lill-pazjenti jew carers li għandhom Physiomer Baby Unidose bil-batch number G239469:

Irritornaw il-prodott bil-batch number **G239469** lill-ispizjar tagħkom.

Tingħataw l-flus lura mill-ispizjerija. L-ispizjar jista' jagħtikom parir fuq prodott alternattiv.

Irrapportaw effetti tas-sigurtà lil Pharmasud Limited billi tibgħat email fuq l-email address li jidher taħt jew lid-Direttorat ta' Tagħmir Mediku fi ħdan l-Awtorità dwar il-Medicini billi tibgħat email fuq mdvigilance.medicinesauthority@gov.mt jew timla l-formola 'Public Incident Report' li tinstab fuq il-website: <https://medicinesauthority.gov.mt/mdforms>

M'hemm l-ebda lok għal thassib jekk int għandek Physiomer Baby Unidose 'batch number' li MHUX dak imsemmi hawn fuq.

Għal aktar informazzjoni

Kuntatt Lokali

Pharmasud Ltd

Chris Vella

Email address:

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

sales@phasmasud.com

Malta Medicines Authority:

Medical Devices and Pharmaceutical Collaboration Directorate

Website: [Medicines Authority \(gov.mt\)](https://www.medicinesauthority.gov.mt)

Email address: mdvigilance.medicinesauthority@gov.mt

Numri tat-telefon : + 356 23439164; +356 23439259; +356 23439261

3, Castille Place, Valletta VLT 2000, Malta
T +356 2200 1700 E press.releases@gov.mt



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 (Figure 1)** 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



PRESS NOTICE



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

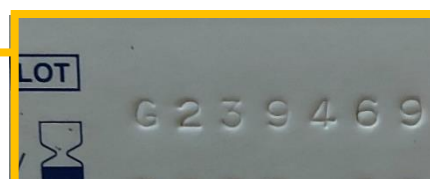


Figure 2B. Batch number

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 \(gov.mt\)](https://www.medicinesauthority.gov.mt)

3, Castille Place, Valletta VLT 2000, Malta
T +356 2200 1700 E press.releases@gov.mt



GOVERNMENT OF MALTA
DEPARTMENT OF INFORMATION

PRESS NOTICE

Email address: mdvigilance.medicinesauthority@gov.mt

Contact Numbers: +356 23439164; +356 23439259; +356 23439261

3, Castille Place, Valletta VLT 2000, Malta
T +356 2200 1700 E press.releases@gov.mt

www.doi.gov.mt