



MEDIA RELEASE

SAHPRA recalls Lubri-A, sterile lubricating gel

Embargo: Immediate release

Pretoria, 19 December 2023 – The South African Health Products Regulatory Authority (SAHPRA) is aware of the product Lubri-A (Sterile Lubricating Jelly) manufactured by Electro-Spyres, classified as Class B medical device and currently being distributed across the country.

SAHPRA has been informed of multiple complaints received from health institutions, both public and private across the country. The complaints are as a result of a number of patients who became ill due to developing a fungal infection, caused by exposure to the fungal species, *Wickerhamomyces anomalus* (previously *Candida pelliculosa*) associated with use of Lubri-A (Sterile Lubricating Jelly).

Lubri-A is available in two presentations, the 2.5 g sachets and 50 g tubes.

Considering the wide usage of the product for lubricating purposes in medical and surgical procedures, the Regulator has taken a decision to urgently recall this product from the market as there are multiple contaminated batches, with the potential to cause serious and widespread nosocomial infections. SAHPRA is alerting healthcare professionals and the public to discontinue the use of the product, remove it from their inventory and return it through their normal distribution channel(s) with immediate effect.

As the source of the contamination of the product is still under investigation and not confirmed, all batches of Lubri-A are being recalled. Future manufacture and distribution of the product will be subject to review and authorisation by SAHPRA.

Classification of the recalls

The recall is being classified as a Class 1, Type A recall, which is associated with a serious product quality concern that may have severe consequences. This is a countrywide recall. The product is being recalled from hospitals, retail outlets, health care professionals, authorised prescribers and individual customers or patients.

What the public should know

Healthcare professionals that have used this product should contact their patients to determine any symptoms of infection after use of product.

The recall is limited to the product called LUBRI-A (2.5g sachets and 50g tubes) and does not affect other lubricating gel products authorised for sale in South Africa.

The contact telephone numbers for Electro-Spyres are:

Landline: 011-608-3998 or 011-402-7208

WhatsApp: +27-82-355-8862

“As a national regulatory authority, the recalling of medical products is a crucial measure to address safety concerns or quality issues so that we protect the health of the public.

SAHPRA is recalling this product from the market as there are multiple suspected contaminated batches with the potential to cause serious and widespread nosocomial infections,” indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

Issued by:

Dr Boitumelo Semete

CEO

boitumelo.semete@sahpra.org.za

For further enquiries /information contact:

Media contact:

Ms Nthabi Moloi

Cell: 082 407 8854

E-mail: nthabi.moloi@sahpra.org.za

About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.

Notes to Editors:

SAHPRA will post this media release on our website. Navigate to the News section on the website.

A podcast will be recorded and posted on the home page. Scroll down the home page to "**SAHPRA TV and Podcasts**". Podcasts appear on the right-hand side.

Should you request an interview for television, please send your request to media@sahpra.org.za and copy melanie.govindasamy@sahpra.org.za. Include your discussion points in your request.

Updates on vaccine registration can be accessed here:

Vaccines - News and updates (sahpra.org.za) - <https://www.sahpra.org.za/news-and-updates/vaccines-news-and-updates/>