

24 November 2025

**L-Arginine (Amargine) 100mg in 1ml Oral Solution Patient Information Leaflet (PIL) error for excipient of known effect (propylene glycol).
Incorrect concentration of propylene glycol stated and requires caution in use statement for babies under 4 weeks old to be included**

Dear Healthcare Professional,

Veriton Pharma Ltd, in agreement with the Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

Summary

- It has been identified that the PIL for L-Arginine (Amargine) 100mg in 1mL Oral Solution states the following incorrect information:
 - Incorrect concentration of the excipient of known effect, propylene glycol. The current PIL states 0.29mg propylene glycol (E1520) per ml, whereas the product L-Arginine (Amargine) 100mg in 1mL Oral Solution contains 1.44mg/ml propylene glycol.
 - In line with EMA guidance on excipients of known effect (EMA/CHMP/302620/2017 Rev. 3: *Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'*), which is followed by the SFDA, the following statements should be included in the PIL if concentration of propylene glycol exceeds 1mg/mL:
 1. "This medicine contains 1.44mg propylene glycol in each ml of L-Arginine."
 2. "If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol".
- As per SFDA guidelines, a list of excipients known to have a recognized action or effect must be stated in the PIL, expressed quantitatively. The PIL Section 2 requires an update in accordance with the EU Guidance on labelling for excipients of known effect, as SFDA follows the EU guidance for propylene glycol requirements.

Further information on the safety concern and the recommendations

Cases of propylene glycol (PG) toxicity have been reported in neonates; however, these occurred at PG exposures much higher than those expected with Amargine, even at a dose of 300 mg/kg/day (equivalent to a PG exposure of 4.32 mg/kg/day). Reported toxicities have included clinical effects such as seizures and biochemical disturbances such as hyperosmolality, lactic acidosis, and elevated plasma creatinine and bilirubin.

Coadministration of Amargine with other medicines containing PG or ethanol may increase total PG exposure and the risk of toxicity. Healthcare professionals are advised to consider the overall PG exposure from all sources and to monitor neonates for clinical and laboratory signs of possible PG toxicity.

Batches already in distribution with the PIL containing incorrect information:

| Batch number | Expiry date | List of countries where impacted batch was distributed |
|---------------------|--------------------|---|
| 1717 | Dec-25 | Saudi Arabia UAE Kuwait |
| 1721 | Jan-26 | Saudi Arabia Jordan |
| 1798 | Jul-26 | Saudi Arabia |
| 1867 | Dec-26 | Saudi Arabia Jordan |
| 1904 | May-27 | Saudi Arabia |
| 1954 | Jun-27 | Saudi Arabia |

Recommendation for labelling concern:

It is recommended that this healthcare professional letter is distributed to all institutions and cascaded to all relevant healthcare professionals that have received these batches of product.

No adverse events/reactions or safety signals related to this deviation have been reported at this stage. Veriton Pharma Ltd will continue to monitor the risk through pharmacovigilance data including adverse event reporting, customer complaint and medical information processes.

Call for reporting

Healthcare Professionals should report any adverse reactions suspected of being due to L-Arginine (Amargine) 100mg in 1ml Oral Solution to Veriton Pharma Ltd:

- Postal address: Veriton Pharma Ltd, Unit 16, Trade City, Avro Way, Brooklands Business Park, Weybridge KT13 0YF
- Email: centralMedicalInformation@veritonpharma.com
- Phone: +44 (0)1932 690325 in office hours (09.00-17:00 UK time) or +44 (0)845 452 4130 outside of the working hours

Local distributor:

- ABDULRAHMAN ALGOSAIBI GENERAL TRADING COMPANY (ALGOSAIBI)
Registered office at P.O. BOX 215 Riyadh 11411, Saudi Arabia
- Phone: +966 58 016 0683
- Email: Safety@aralgosaibico.com

Healthcare Professionals should report any product complaints or adverse events suspected to be associated with the use of L-Arginine (Amargine) 100mg in 1ml Oral Solution through their spontaneous national reporting system.

Contact point

If you have any questions, please contact:

National Pharmacovigilance Center (NPC) – Saudi Food & Drug Authority (SFDA):

Call Center: 19999

Email: npc.drug@sFDA.gov.sa

Website: <https://ade.sFDA.gov.sa>



Yours sincerely,

Marc Haim

Quality Director

Marc HAÏM

Electronically signed by: Marc
Haim
Reason: I approve this document.
Date: 24-Nov-2025 16:04:01 GMT+1

Anne Lethbridge-Smith

Senior Manager Pharmacovigilance



Electronically signed by: Anne
Lethbridge-Smith
Reason: I approve this document.
Date: 24-Nov-2025 17:13:23 GMT










Dear HCP Letter v2

Final Audit Report

2025-11-24

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