

Camurus AB,
Lund, Sweden

29 JAN 2025

Dear Healthcare Professional Communication

Concerning: Buprenorphine, Buvidal prolonged-release solution for injection

Notification of re-labelling of Buvidal due to extension of shelf-life

Summary:

Camurus AB would like to inform you that the shelf-life of Buvidal prolonged release solution for injection has been extended. As a consequence, Buvidal packs already available on the Saudi market was, after agreement with SFDA, indicated on the outer pack of Buvidal by adding a sticker with the new expiry date on the outer package. The syringe label remained unchanged. For that reason, for batches listed below there are two different expiry dates where the valid expiry date is the found on the outer pack.

- **Outer pack Expiry Date:** 30 August 2025
- **Syringe label Expiry Date:** 30 August 2024

Product	Reg.no.	Lot No.	Old Expiry date (24 months)	New Expiry date (36 months)
Buvidal 16mg inj	808222427	Z0184A	30-Aug-2024	30-Aug-2025
Buvidal 24mg inj	808222426	Z0185A	30-Aug-2024	30-Aug-2025
Buvidal 32mg inj	808222430	Z0186A	30-Aug-2024	30-Aug-2025
Buvidal 64mg inj	808222429	Z0187A	30-Aug-2024	30-Aug-2025
Buvidal 96mg inj	2908222557	Z0188A	30-Aug-2024	30-Aug-2025
Buvidal 128mg inj	808222431	Z0189A	30-Aug-2024	30-Aug-2025

Further information on the safety concerns and recommendations: The quality of the product medication is unchanged until the expiry dates indicated on the outer pack (30 August 2025). There is no change to the benefit-risk profile of the product. HCPs administering the product are advised to refer to the label on the outer pack for correct expiry date.

Call for reporting:

Healthcare professionals should report suspected adverse reactions/ product quality complaints associated with this product in accordance with the national spontaneous reporting system:

The National Pharmacovigilance Centre (NPC) at Saudi Food and Drug Authority (SFDA)
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: <http://ade.sfda.gov.sa/>

For further information, please contact the local distributor: Abdulrehman Algosaibi G.T.C, Pharmacovigilance Department, Mobile: +966580160683, Email: safety@aralgosaibico.com

Kind regards,



Electronically signed by: Johanna Strandell
Reason: I am the approver
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Johanna Strandell,
Director Patient Safety and QPPV



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Lina Åkesson
Director Quality Operations and RP