

GALDERMA

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April 12, 2023

Voluntary Precautionary Recall of Epiduo Forte® Gel under HK-66483

[Hong Kong 12-Apr-2023] The Department of Health (DH) today (12-Apr-2023) endorsed Galderma Hong Kong Limited, a licensed wholesaler to conduct a voluntary recall of one (1) batch of the below product as a precautionary measure.

Epiduo Forte® Gel Lot 359448 (15g pump) presents out of specification (OOS) results for Benzoyl Peroxide (BPO) assay after 12 months of a routine stability study. The most probable cause identified at this moment is linked to the 15g pump not being sufficiently “airtight” leading to water evaporation and to the concentration of active ingredient in the gel mostly on the top fraction of the bottle. The affected batch is recalled on a precautionary measure.

Product Name	Pack Size	HK Reg. No.	Lot Number	Expiry Date
Epiduo Forte® Gel	15g bottle/box	HK-66483	359448	06/2023

Galderma has performed a Preliminary Patient Safety Risk assessment on Epiduo Forte® gel which confirms the absence of risk of the patients using the impacted lot.

As of 28-Mar-2023, no adverse event reports with the concerned batches have been received in Galderma global safety database.

The above batch has been supplied to private hospitals, private doctors and re-exported to Macau. The proposed recall is up to hospital and doctor level only.

Galderma Hong Kong has set up a dedicated recall hotline (+852-9545 6993) to handle related enquiries.

Galderma Hong Kong will closely monitor the recall and report to DH as appropriate. So far, Galderma has not received any adverse reaction reports in connection with the impacted batch.