PHARMACEUTICAL
COSMETICS AND
OVER THE COUNTER PRODUCTS

Unit 10 Ashbourne Business Park, Rath, Ashbourne, Co. Meath
Tel.: 01 83 567 00 Fax: 01 83 567 10

BATCH RECALL

Lipocomb 10 mg/10 mg hard capsules, PPA0465/460/001
Lipocomb 20 mg/10mg hard capsules, PPA0465/460/002

Product Name	PPA Number	Batch Number on carton	Batch Number on blister sticker label	Expiry Date
Lipocomb 10 mg/10 mg hard capsules	PPA0465/460/001	5466A0722::RN220	5466A0722	07/2025
Lipocomb 20 mg/10 mg hard capsules	PPA0465/460/002	L803D0822::RN228	L803D0822	08/2025

September 14th, 2023

Dear Pharmacist,

As discussed via telephone on 14th September 2023, we wish to advise that the above batches of Lipocomb 10 mg/10 mg, hard capsules, PPA0465/460/001 and Lipocomb 20 mg/10mg hard capsules, PPA0465/460/002 are being recalled with immediate effect.

This recall is going to **patient level** and has been agreed with Health Products Regulatory Authority (HPRA).

The recall is being initiated due to a product mix up issue due to incorrect labelling. It is possible that blisters contained within packs of Lipocomb 10 mg/10 mg hard capsules actually contain Lipocomb 20 mg/10 mg hard capsules. It is also possible that blisters contained within packs of Lipocomb 20 mg/10 mg actually contain Lipocomb 10 mg/10 mg capsules.

Lipocomb 10 mg/10 mg hard capsules have a yellow coloured cap and yellow coloured body. Lipocomb 20 mg/10 mg hard capsules have a caramel coloured cap and yellow coloured body.

Our records show that your pharmacy was supplied with units from one or more of the above listed batches and, on that basis, we kindly request that you perform the following actions:

1. Immediately quarantine any units from the above batches which you have in your pharmacy or returned to you.

2. Please immediately check your dispensing records to identify patients to whom any packs of the above products were dispensed since **8th August 2023 (Lipocomb 10 mg/10 mg hard capsules)** and since **24th August 2023 (Lipocomb 20 mg/10 mg hard capsules).**

3. If any patients are identified during this check, please contact the patient or their carer to check if they have an impacted batch in their possession. They should be instructed to check the batch number printed on the carton, or printed on the sticker on the product blisters. Please advise the patient not to use the impacted pack and to return the impacted pack to their pharmacy at their earliest opportunity to obtain a pack from an unimpacted batch.

4. Please contact PCO's Sales Support Team on 01-8356700 to arrange uplift of quarantined units within the next 14 days. Credit will be arranged at that time.

If you have supplied units of the above batches to another pharmacy or clinic, please forward a copy of this letter to them so that they can perform the requested actions.

Should you have any queries in relation to the recall, please contact Niamh Clarke at 01-8356700.

Yours sincerely,

Niamh Clarke, MPSI, QP
Head of Quality & Regulatory Affairs
Phone: 01 8356700
Email: nclarke@pco.ie