

Direct Healthcare Professional Communication (DHPC) Letter

7 September 2025

Triglycerides Medium-chain, Soya oil , Omega-3-acid triglycerides (Lipoplus®20%) emulsion for infusion 100 ML, 250 ML– Important information on subvisual agglomerates, use of an infusion filter for fat emulsions

Dear Healthcare professional, the marketing authorisation holder B.Braun in agreement with Saudi Drug and Food Authority (SFDA) would like to inform you of the following:

Summary

- *In stability studies, agglomerates of droplet-like structures were detected in individual batches of the finished medicinal product. These structures are composed of components of the emulsion and can form during the shelf life.*
- *Therefore, the emulsion for infusion must be administered with an infusion filter for fat emulsions with a pore size of 1.2 µm (Intrapur® Lipid – 1.2 µm infusion filter for fat emulsions and mixed solutions, B. Braun, or equivalent filter).*
- *If it cannot be guaranteed that an appropriate filter is used, Lipoplus® emulsion should not be used for more than 12 months, which means one year less than labelled on the packaging.*

Background on the safety concern

In ongoing stability tests, subvisual droplet-like structures of emulsion components were detected in individual batches during the test for subvisual particles in accordance with the European Pharmacopoeia. This phenomenon was only observed at 25°C storage (according to the prescribing information) for more than 12 months. The earliest time of detection was 18 months. At higher temperatures, this effect may occur earlier.

Intravenous administration of the droplet-like structures can lead to adverse events such as embolism in the capillary tissue of the lungs. There are currently no reports of adverse events related to Lipoplus® emulsion for infusion and the topic described. Apart from the observed structures, the product does not show any abnormalities over the shelf life.

Until further notice, in the interest of patient safety, a lipid emulsion filter with a pore size of 1.2 µm (tested filter material: Intrapur® Lipid – 1.2µm infusion filter for fat emulsions and mixed solutions, uncharged 1.2 µm filter membrane made of polyethersulfone, B. Braun Melsungen AG) must be used.

If (e.g. in the case of patient-specific parenteral nutrition or due to internal processes) it cannot be assured that an appropriate filter is used, Lipoplus® Emulsion should not be used for more than 12 months (shelf life therefore one year less than stated on the package; e.g. 10/2026 can be used without restrictions until 10/2025).



Call for reporting

Please report any suspected adverse reactions associated with the use of Lipoplus® in accordance with the national requirements to:

B.Braun, Saudi Arabia

Email: bsafety@mediserv.com.sa



The National Pharmacovigilance Centre (NPC)

Land Line: 19999.

Web-page: <http://ade.sfda.gov.sa>

Email: npc.drug@sfda.gov.sa

QR code:



Sincerely,

Azizah Alsohaibani

local QPPV for B.Braun, Saudi Arabia

Azizahalsohaibani