28.08.2025

Lipidem® / Lipoplus® emulsion for infusion (10 x 500 ml, 10 x 250 ml, glass bottles; PZN 04237727; 04237733) – Important information on subvisual agglomerates, use of an infusion filter for fat emulsions

Dear Healthcare professional, the marketing authorisation holder B. Braun Melsungen AG in agreement with the Hessian State Office for Health and Care 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 Melsungen AG, or equivalent filter).***
- ***If it cannot be guaranteed that an appropriate filter is used, Lipidem® / 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 Lipidem® / 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, Lipidem® 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

Reporting suspected adverse drug reactions after approval is of great importance. It enables continuous monitoring of the benefit-risk ratio of the drug. Healthcare professionals are required to report any suspected adverse reaction to the marketing authorisation holder.

B. Braun Melsungen AG - Global Pharmacovigilance and Patient Safety Department
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Alternatively, suspected adverse drug reactions can also be reported to

Federal Institute for Drugs and Medical Devices (BfArM)
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn
Fax: +49 (0)228 207 5207
written
or electronically via the internet (www.bfarm.de – Medicinal products – Pharmacovigilance – Reporting risks)

Company contact point:

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