

## Baxter - Recall of Intralipid® 20% (intravenous [IV] fat emulsion)

- On October 5, 2017, <u>Baxter announced</u> a voluntary, user level recall of one shipment from one lot of <u>Intralipid 20% (IV fat emulsion)</u> due to exposure to subfreezing temperatures during transit to a distribution facility.
- The recalled lot was distributed to hospitals and healthcare providers between 8/11/2017 and 8/31/2017. Other shipments of the lot below were not affected by this issue.

Product Description	NDC#	Lot# (expiration date)
Intralipid 20% IV fat	0338-0519-58	10LE9597 (4/1/2019)
emulsion, 100 mL		

- Intralipid is indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition for extended periods of time (usually for more than 5 days) and as a source of essential fatty acids for prevention of essential fatty acid deficiency.
- Subfreezing temperature is outside of the acceptable storage range listed on the Intralipid product labeling. If accidentally frozen, Intralipid 20% should not be used. When subjected to freezing, the emulsion droplets will increase in size, forming aggregates that can block pulmonary circulation and lead to serious adverse health consequences that can be life-threatening.
  - To date, Baxter has not received any reports of associated adverse events or product complaints.
- Recalled product should be removed and returned to Baxter for credit by contacting the Baxter Healthcare Center for Service at 888-229-0001.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the recalled product.
- Patients with questions regarding this recall may contact Baxter Corporate Product Surveillance at 800-437-5176.



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