FRESENIUS KABI
caring for life

HOW IT STARTED

"I was really scared when I found out there were complications with my bowel surgery and I needed to be on the ICU. I was so worried about what would happen to me – but the doctors were amazing and, thankfully, I'm now almost back to my old self"

HOW IT'S GOING

For your ICU and surgical patients requiring parenteral nutrition

SMOFlipid®

Soya-bean oil, medium-chain triglycerides, olive oil, fish oil

*...with a little bit of TLC**

**Trusted Lipid Care*

Prescribing information and references can be found on page 4

SMOFlipid: a trusted 4-oil intravenous lipid emulsion with over 10 years' real-world experience...[1]

HOW IT STARTED

"Unfortunately I ended up on ICU after my bowel surgery. My gut stopped working and as well as all the other treatments, I was put on parenteral nutrition. It was awful having to lie there not knowing how long I'd be there, if I'd make a full recovery, or even if I'd ever eat normally again"

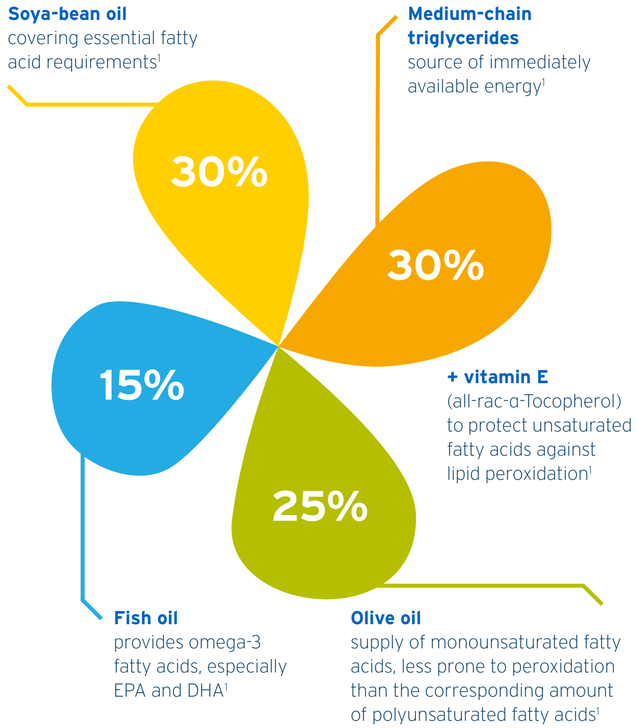
MEET LAURETTE

- Laurette is 55 years old
- Following bowel surgery, she developed complications and intestinal failure, and was transferred to the ICU
- Laurette was at risk of malnutrition and required parenteral nutrition for one week[2,3]

SMOFlipid - a 4-oil mix that provides energy and essential fatty acids, with a profile designed to support recovery.[1]

No other lipid emulsion brand has the same 4-oil mix and fatty acid profile as SMOFlipid.[1,4-7]

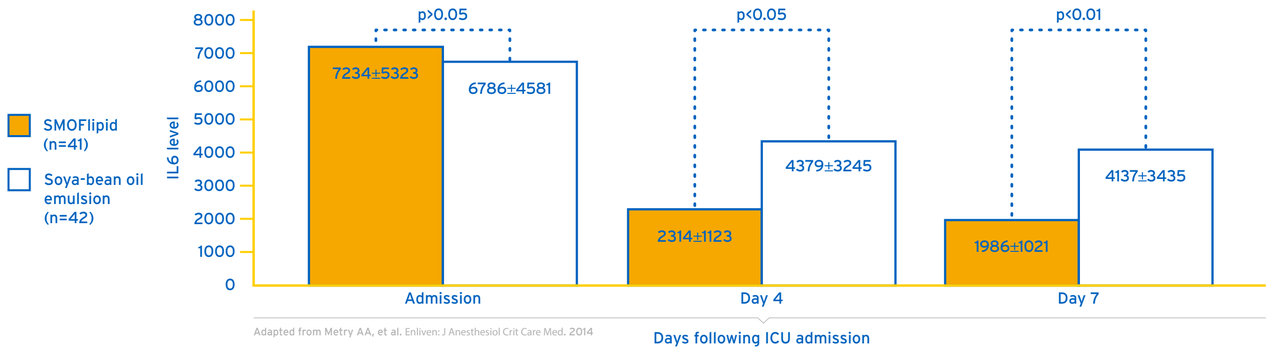
SMOFlipid is indicated as a supply of energy and essential fatty acids and omega-3 fatty acids to patients, as part of a parenteral nutrition regimen, when oral or enteral nutrition is impossible, insufficient or contraindicated.[1]



SMOFlipid: demonstrated tolerability in post-operative patients[8]

- SMOFlipid demonstrated similar tolerability in post-operative patients compared to a standard soya-bean oil emulsion[8]
- An ESPEN expert group supports the use of olive oil and fish oil in the nutritional care of ICU patients, with evidence suggesting that parenteral nutrition enriched with fish oil may reduce the rate of complications versus standard parenteral nutrition for surgical ICU patients[9]
- SMOFlipid's fatty acid composition may have several beneficial effects for the immune system and may result in a shorter length of hospitalisation compared to a standard soya-bean oil emulsion[8,10]

Patients receiving SMOFlipid have shown lower levels of pro-inflammatory IL6 compared to a standard soya-bean oil emulsion[11]*



Adapted from Metry AA, et al. Enliven: J Anesthesiol Crit Care Med. 2014

*Significantly lower mean IL6 levels at Day 4 and Day 7, in a prospective randomised trial in n=83 post-surgical ICU adults receiving parenteral nutrition[11]

Figures shown are mean ± standard deviation

HOW IT'S GOING

Laurette received SMOFlipid as part of a package of care that aimed to support her nutritional status during her week on the ICU[2,12]

"I was really ill when I was on the ICU and I didn't know if I would make a full recovery – it was an incredibly scary and stressful time. I had to have parenteral nutrition to help to support my recovery and give my gut time to heal, which took some of the stress away. Now I'm eating normally again and feeling much more positive about my future"

For over 10 years, we've worked with the same trusted 4-oil formulation. **Laurette is one example of the millions of patients who have been prescribed SMOFlipid.**[1,13]

As times are changing, we're working with clinicians and patients to help provide the support they need. We're part of a wider package of care, aiming to improve the lives of adults, children and infants.

They are why we keep going.
For the next 10 years, and beyond.

Speak with your Fresenius Kabi representative to discuss how SMOFlipid can help support your ICU and surgical patients

SMOFlipid®

Soya-bean oil, medium-chain triglycerides, olive oil, fish oil

Abbreviated prescribing information

SMOFlipid 200mg/ml emulsion for infusion. Active ingredients: 1000ml contains: Soya-bean oil (refined) 60g, Medium-chain triglycerides 60g, Olive oil (refined) 50g, Fish oil (rich in omega-3-acids) 30g. 1000ml emulsion contains up to 5 mmol sodium.

Indications: Supply of energy and essential fatty acids and omega-3 fatty acids to patients, as part of a parenteral nutrition regimen, when oral or enteral nutrition is impossible, insufficient or contraindicated.

Dosage and administration: Intravenous infusion into a peripheral or central vein. The dosage and infusion rate should be governed by the patient's ability to eliminate fat. Adults – standard dose is 1.0–2.0g fat/kg body weight (bw)/day (5–10 ml/kg bw/day). Recommended infusion rate is 0.125g fat/kg bw/hour and should not exceed 0.15g fat/kg bw/hour, corresponding to 0.75ml SMOFlipid/kg bw/hour. Children – infusion rate should not exceed 0.15g fat/kg bw/hour. Increase daily dose gradually over the first week of administration. The maximum recommended daily dose is 3g fat/kg bw/day, corresponding to 15ml SMOFlipid/kg bw/day. Neonates and infants – initial dose should be 0.5–1.0g fat/kg bw/day followed by a successive increase of 0.5–1.0g fat/kg/bw/day up to 3.0g fat/kg bw/day (corresponding to 15ml SMOFlipid/kg bw/day). The infusion rate should not exceed 0.125g fat/kg bw/hour. In premature and low birthweight neonates, infuse SMOFlipid continuously over about 24 hours. Administer as part of a complete parenteral nutrition treatment including amino acids and glucose. When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed.

Contraindications: Hypersensitivity to fish-, egg-, soya- or peanut protein, or to any of the active substances or excipients, severe hyperlipidaemia, severe liver insufficiency, severe blood coagulation disorders, severe renal insufficiency without access to hemofiltration or dialysis, acute shock, general contraindications to infusion therapy, unstable conditions (see SmPC).

Special warnings and precautions for use: Monitor individual's capacity to eliminate fat. Dose reduction or cessation of infusion should be considered if serum or plasma triglyceride concentrations during or after infusion exceed 3mmol/L. Use with caution in conditions of impaired lipid metabolism, in patients with marked risk for hyperlipidemia, in neonates and premature neonates with hyperbilirubinemia and/or pulmonary hypertension. Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. Contains soya-bean oil, fish oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been seen between soya-bean and peanut. Administration of medium-chain fatty acids alone can result in metabolic acidosis; simultaneous infusion of carbohydrate or a carbohydrate-containing amino acid solution is recommended. Laboratory tests generally associated with monitoring of intravenous nutrition should be checked regularly. Monitor blood platelet counts, liver function tests and serum triglycerides in neonates. Any sign or symptom of anaphylactic reaction should lead to immediate interruption of the infusion. High plasma lipid levels may interfere with some laboratory blood tests.

Undesirable effects: Common – slight increase in body temperature. Uncommon – lack of appetite, nausea, vomiting, chills. Rare – hypotension, hypertension, dyspnoea, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Very rare – priapism. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details.

Legal Category: POM.

Marketing Authorisation Number: PL 08828/0166.

Marketing Authorisation Holder: Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK.

Package Size and Cost: UK: 100ml £7.44, 250ml £11.90, 500ml £17.43.

Further information: Prescribers should consult the summary of product characteristics (SmPC) in relation to other **adverse reactions**.

Adverse events should be reported at https://yellowcard.mhra.gov.uk and to Fresenius Kabi Limited.

Date of Preparation: June 2020.

Abbreviations

bw, body weight; DHA, docosahexaenoic acid; EPA, eicosapentaenoic acid; ESPEN, European Society for Clinical Nutrition and Metabolism; IL6, interleukin 6; POM, prescription only medicine

References

1 SMOFlipid 200mg/ml emulsion for infusion Summary of Product Characteristics. Fresenius Kabi Limited. March 2020.
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7 ClinOleic 20%, emulsion for intravenous infusion Summary of Product Characteristics. Baxter S.A. May 2021.
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10 Grimm H, et al. Improved fatty acid and leukotriene pattern with a novel lipid emulsion in surgical patients. *European Journal of Nutrition*. 2006;45:55–60.
11 Metry AA, et al. SMOFlipid verus intralipid in postoperative ICU patients. *Enliven: J Anesthesiol Crit Care Med*. 2014;1(6):015.
12 Singer P, et al. ESPEN guideline on clinical nutrition in the intensive care unit. *Clinical Nutrition*. 2019;38:48–79.
13 Data on file.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk Adverse events should also be reported to Fresenius Kabi Limited. Email: Pharmacovigilance.GB@fresenius-kabi.com

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