

HOW IT STARTED



"My son Bailey was born at 27 weeks. He was tiny and had to fight for survival. Bailey received parenteral nutrition as part of a package of care that supported his growth and development at the start of his life"

HOW IT'S GOING



For your
neonatal
patients
requiring
parenteral
nutrition

SMOF^{lipid}[®]

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

*...with a little
bit of TLC**
**Trusted Lipid Care*

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

HOW IT STARTED



“When Bailey was born we were very concerned about his low birth weight. He was so small and we didn't know what it would mean for his development”

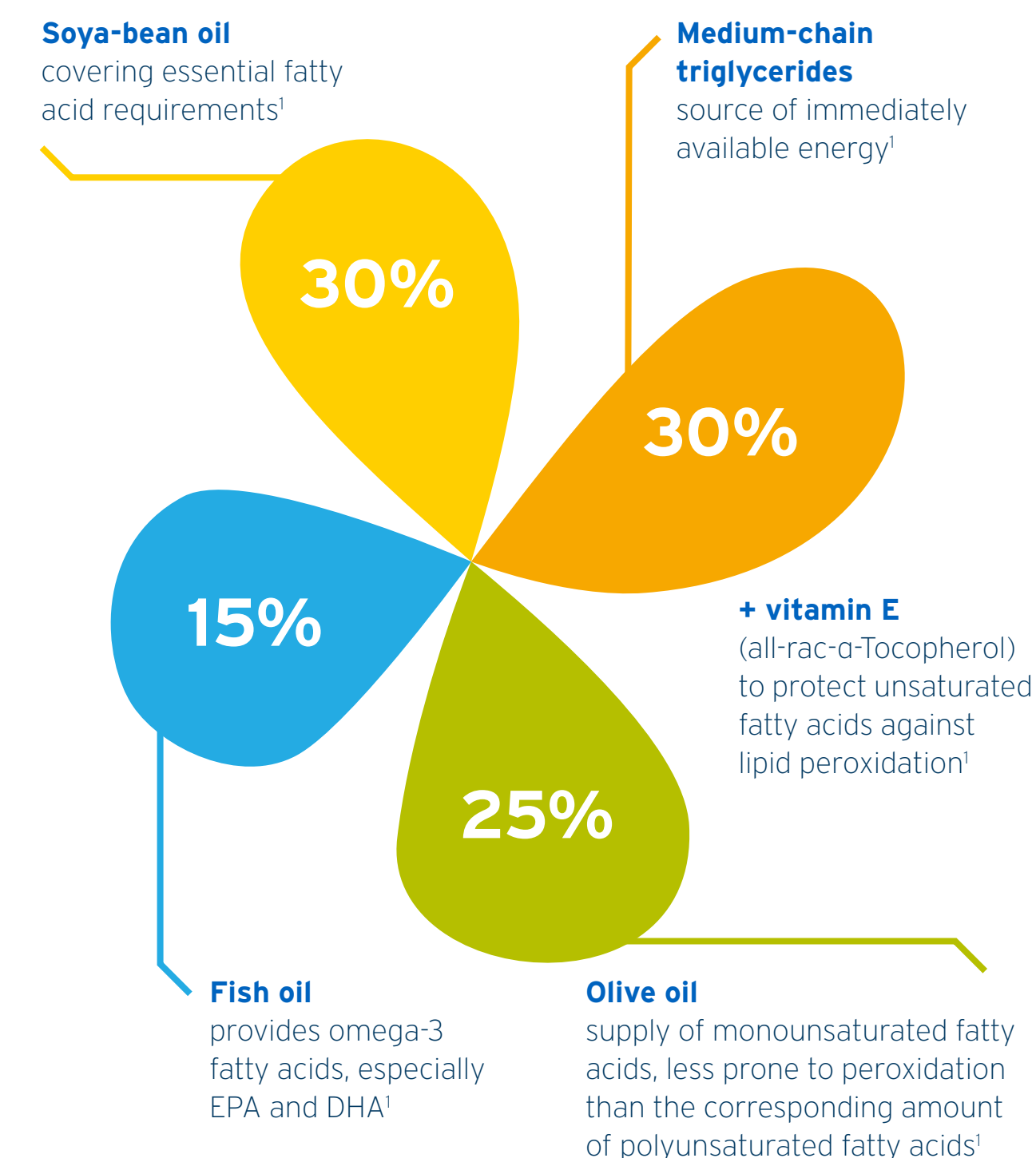
MEET BAILEY

- Bailey was born prematurely at 27 weeks²
- He had an extremely low birth weight of 975g²
- He required parenteral nutrition to support weight gain²
- Bailey received SMOFlipid as part of a parenteral nutrition regimen for 11 days²

SMOFlipid - a 4-oil mix that provides energy and essential fatty acids, with a profile designed for metabolic compatibility.¹

No other lipid emulsion brand has the same 4-oil mix and fatty acid profile as SMOFlipid.^{1,3-6}

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

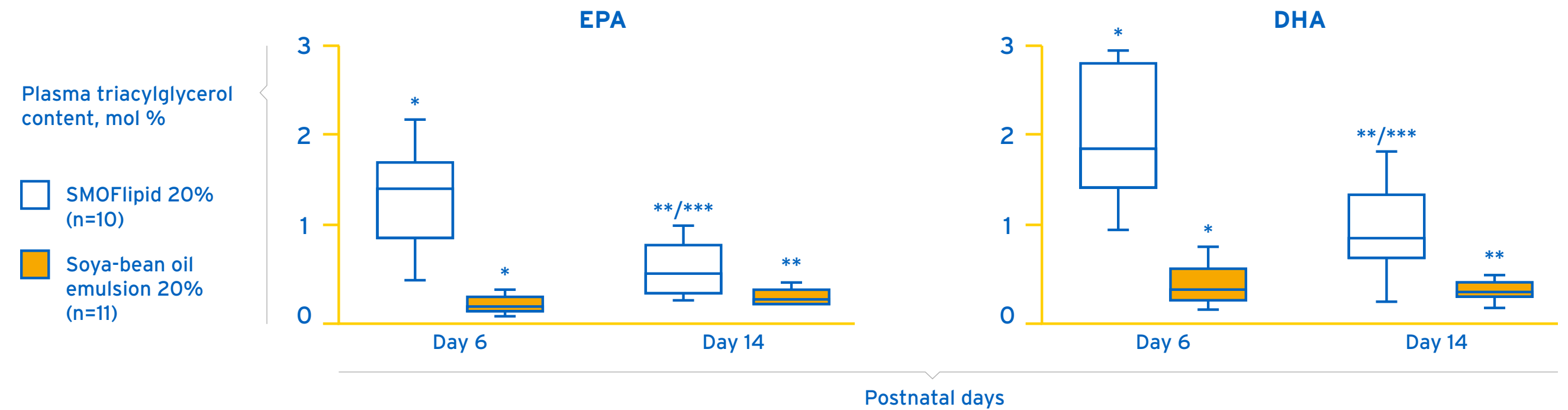


SMOFlipid: demonstrated similar tolerability in premature infants compared to soya-bean oil or olive-oil based lipid emulsions⁷⁻⁹

Compared to soya-bean oil emulsion, SMOFlipid has been shown to:

- Increase plasma triacylglycerol⁹ and phospholipid^{2,9} EPA and DHA concentrations leading to an improved plasma fatty acid profile, and lower plasma phytosterol concentration in very low birth weight infants²
- Enhance head circumference growth and weight gain in pre-term neonates^{2,10}
- Reduce the mean duration of hospitalisation by approximately 1 week (SMOFlipid [n=48]: 87.1+/-26.5 days vs soya-bean oil [n=48]: 93.9+/-33.6 days, p=0.327)²

EPA and DHA play a crucial role in neurodevelopment and immune function, and have been shown to be increased in very low birth weight neonatal patients receiving SMOFlipid compared to soya-bean oil emulsion²



Box and whisker plots indicate medians, interquartile ranges and the 2.5th and 97.5th percentiles
 *There was a significant difference (p<0.05) between the study group and the control group on Day 6
 **There was a significant difference (p<0.05) between the study group and the control group on Day 14
 ***There was a significant change from Day 6 to 14 (p<0.05)²



HOW IT'S GOING

- Bailey gained 250g in weight and 15mm in head circumference over 14 days²
- After 14 days Bailey was receiving full enteral nutrition²

“Parenteral nutrition was really important in the early days of Bailey’s life. It was reassuring to know that he was receiving the nutrients he needed to keep growing and developing. He’s now a happy healthy little boy, you wouldn’t know that he was born prematurely”

For over 10 years, we've worked with the same trusted 4-oil formulation. **Bailey is one example of the millions of patients who have been prescribed SMOFlipid.**^{1,11}

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 neonatal 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.

 **FRESENIUS KABI**
caring for life

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Date of Preparation: June 2023 | UK-SMOF-2300002

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; POM, prescription only medicine

References

- 1 SMOFlipid 200mg/ml emulsion for infusion Summary of Product Characteristics. Fresenius Kabi Limited. March 2020.
- 2 Vlaardingerbroek H, et al. Growth and fatty acid profiles of vlbw infants receiving a multicomponent lipid emulsion from birth. *Journal of Pediatric Gastroenterology & Nutrition*. 2014;58:417-27.
- 3 ClinOleic 20%, emulsion for intravenous infusion Summary of Product Characteristics. Baxter S.A. May 2021.
- 4 Lipidem 200mg/ml emulsion for infusion Summary of Product Characteristics. B. Braun Limited. July 2020.
- 5 Anez-Bustillos L, et al. Review: Lipid Formulations for the Adult and Pediatric Patient: Understanding the Differences. *Nutrition in Clinical Practice*. 2016;31:596-609.
- 6 Lipofundin MCT/LCT 20%, emulsion for infusion Summary of Product Characteristics. B. Braun Limited. December 2019.
- 7 Deshpande G, et al. Fish oil (SMOFlipid) and Olive Oil Lipid (Clinoleic) in Very Preterm Neonates. *Journal of Pediatric Gastroenterology and Nutrition*. 2014;58:177-82.
- 8 Tomsits E, et al. Safety and efficacy of a lipid emulsion containing a mixture of soybean oil, medium-chain triglycerides, olive oil, and fish oil: a randomised, double-blind clinical trial in premature infants requiring parenteral nutrition. *Journal of Pediatric Gastroenterology and Nutrition*. 2010;51:514-21.
- 9 Rayyan M, et al. Short-term use of parenteral nutrition with a lipid emulsion containing a mixture of soybean oil, olive oil, medium-chain triglycerides, and fish oil: A randomized double-blind study in preterm infants. *Journal of Parenteral and Enteral Nutrition*. 2012;36:815-945.
- 10 Bin-Nun A, et al. Head Circumference Growth Is Enhanced by SMOFlipid in Preterm Neonates. *American Journal of Perinatology*. 2020;37:1130-3.
- 11 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