CLINICAL NUTRITION

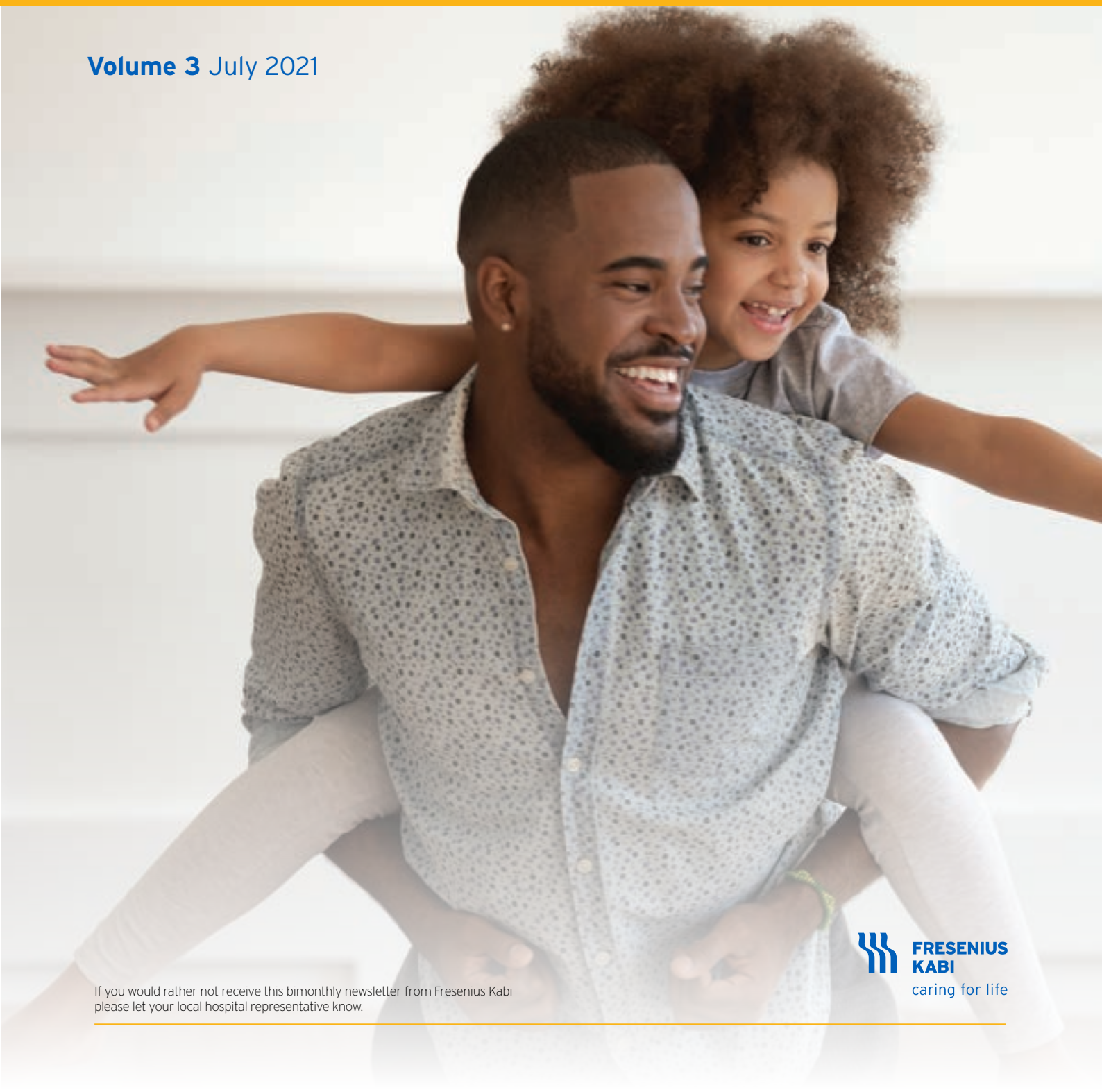
UPDATE

From **Fresenius Kabi**

In this issue:

Parenteral nutrition **Home parenteral nutrition** **Educational opportunities**

Volume 3 July 2021



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WELCOME

to the third edition of the Fresenius Kabi PN (parenteral nutrition) Service Update.

What a few weeks they have been... Just as COVID numbers in hospitals were reducing, a cyber-attack occurred. This posed major challenges in communicating, particularly for the clinicians looking after HPN patients as we were in the middle of changing all scripts for trace elements. This is now completed and we would like to thank all involved for their diligence and patience.

This edition provides an update on personnel changes, compounded bags, HPN patient survey results and education opportunities available, as well the recurring 'Introducing' article to allow you to familiarise yourselves with the Fresenius Kabi PN team and put some faces to names.

We would welcome your feedback on what you would like to see included so that we can ensure you get the most out of this communication and it remains relevant for you and your teams.

Please address feedback to megan.hearty@fresenius-kabi.com.

Specific product information will also be included to keep you informed of important product changes or updates. Prescribing information on these products will be available on the back of the newsletter.

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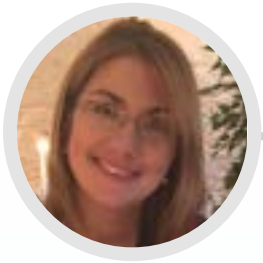
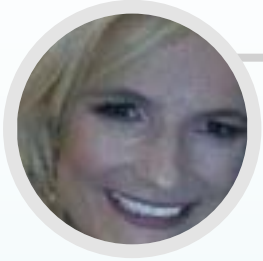
Personnel update



Our Homecare Manager Myra O Neill, nurse advisor Avril Duignan, and Homecare Coordinator Sam Rioch all left the company last month to follow new ventures.

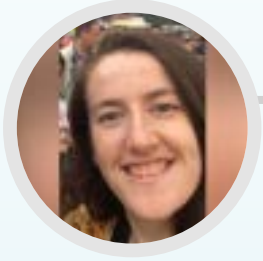
Niamh Donnelly will now be responsible for leading Homecare operations and process enhancements.

Veronica Lee will replace Avril Duignan and continue to support Richard Lanigan and Maggie McMahon in providing our excellent nursing service.



Michelle Keane will replace Sam Rioch and work alongside Edel Tennant and Jennie Bonney.

Edel Tennant has been promoted to the role of Homecare Team Lead. She will co-ordinate activities and lead the implementation of service and process enhancements within Homecare. Jennie will now look after ROI HPN patients and Michelle will look after NI HPN patients.



Claire Toland has been promoted to the role of Associate Parenteral Nutrition Product Manager. She will assist Niamh and provide day-to-day support for Parenteral Nutrition and Homecare.

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Team members

Introducing...

Edel Tennant

Homecare Co-ordinator Fresenius Kabi Ireland

Hi, I'm Edel and I work as a Homecare Co-ordinator in the Homecare Department alongside Michelle, Jennie, and Gillian in the office based in Balbriggan, County Dublin. I have worked in this role for the past 5 years.

As Homecare Co-ordinators we provide parenteral nutrition and all ancillary requirements to our home patients in Northern Ireland and Southern Ireland on a weekly basis. We are 100% patient focused.

Although we don't get to physically meet our patients, we liaise with them by phone on a regular basis and over time we build up strong relationships with them. We liaise with dietitians and nurses on a daily basis regarding current and potential new patients.

When a new patient is referred to our service, we have to submit the funding applications to the local HSE offices. Once funding has been approved and the patient has been assessed, our nurses Richard, Maggie and Veronica will start the training with the patients and their carers.

Every day is different. We are very much a 'reactive service'; you could have your whole day planned out and then you arrive into office in the morning and your day could change with one phone call or email.

Over the past 5 years I have encountered many challenges with the supply of parenteral nutrition. Whether it be the 'Beast from the East' causing havoc with the weather or Covid-19 and Brexit delaying the delivery of parenteral nutrition from the compounding units in the UK, I am happy to say that on every occasion, no matter how difficult the situation was, all our home patients never went without their parenteral nutrition.

Our home patient delivery drivers really go above and beyond with the service they provide. Teamwork makes the dream work - and I must say I work alongside a fantastic team.

Away from work, I like to relax and unwind. I enjoy watching criminology documentaries and programmes. I am a football fanatic; I've supported Liverpool since I was a teenager. I've been to Anfield many times and one of the highlights of 2020 for me was Liverpool winning the premier league.

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Team members

Introducing...
Richard Lanigan

Clinical Nurse Adviser

Hi, my name is Richard Lanigan. I started working with Fresenius Kabi in 2009.

I qualified as a general nurse in Paddington, London in 2005. I returned to Dublin in 2006 to work as a general nurse in St James' hospital. I really enjoyed my time there and I'm fortunate to get to visit wards in St James' regularly as part of my role.

I have been working as a Clinical Nurse Adviser since 2009.

Back then I was the lone nurse, and our nursing and homecare department has grown significantly since. We also now closely work with various nursing companies to deliver patient care.

In 2019 I achieved a level 3 award in education and training. It was very beneficial to learn new ways to teach and train.

Outside work I love to watch most sports and to listen to a wide array of music. I have managed to get over the line of the last three Dublin city marathons and I continue to run and hope to do this year's one if it goes ahead. I am also guilty of possessing a dry robe - this was probably one my better purchases as anyone that's dipped in the Irish sea in winter will agree.

I'm married to Linda and have three children, Maisie 12, Amelia 9 and Richie 8.

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A REMINDER

Additrace®
(iron, zinc, manganese, copper, chromium, selenium, molybdenum, fluoride, iodine)

and Additrace N®
(chromium, copper, iron, manganese, iodine, fluoride, molybdenum, selenium, zinc)

Additrace N was developed from the profile of Additrace aligned with the latest A.S.P.E.N recommendations for multi-trace element preparations for use in adult parenteral nutrition.[1]

The table below outlines the differences between Additrace and Additrace N. Prescribing information available on page 17. Always refer to the Summary of Product Characteristics before prescribing.

Content in 10ml (one ampoule)	**Additrace[2]**	**Additrace N[3]** (Direction of content change from Additrace indicated by arrows.)
Iron	1.1mg (20µmol)	1.1mg (20µmol)
Molybdenum	19µg (0.2µmol)	19µg (0.2µmol)
Chromium	10µg (0.2µmol)	10µg (0.2µmol)
Zinc	6.5mg (100µmol)	↓ 5mg (77µmol)
Fluoride	0.95mg (50µmol)	0.95mg (50µmol)
Iodide	130µg (1µmol)	130µg (1µmol)
Manganese	275µg (5µmol)	↓ 55µg (1µmol)
Selenium	32µg (0.4µmol)	↑ 79µg (1µmol)
Copper	1.3mg (20µmol)	↓ 0.38mg (6µmol)

Additrace N 10mls vial will become available later in the year

References

1. Vanek V, Borum P, Buchman A, et al. ASPEN position paper: recommendations for changes in commercially available parenteral multivitamin and multi-trace element products. Nutr Clin Pract. 2012;27(4):440-91.
2. Additrace Summary of Product Characteristics. Fresenius Kabi Deutschland Gmbh. March 2020
3. Additrace N Summary of Product Characteristics. Fresenius Kabi Deutschland GmbH. March 2020

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3CBs

A reminder of the new 3CB bags, SmofKabiven® Low Osmo and SmofKabiven Extra Nitrogen, that have been made available in the range recently. SmofKabiven Extra Nitrogen contains electrolytes but is also available as an electrolyte free version.

SmofKabiven Extra Nitrogen

(amino acids +/- electrolytes, glucose, lipid emulsion)

An option for your patients when meeting protein targets without overfeeding is a priority – ratio of amino acids (AA) to total calories is 1g AA : 20kcal

Prescribing information available on page 18. Always refer to the Summary of Product Characteristics before prescribing.

SmofKabiven Extra Nitrogen[1]/ SmofKabiven Extra Nitrogen Electrolyte Free[2]	11gN	16gN	21gN
Total energy (approx.) (kcal)	900	1350	1800
Non-protein calories (approx.) (kcal)	635	952	1270
Volumes (ml)	1012	1518	2025
Amino acids (g)	66.3	99.4	133
Nitrogen (g)	10.6	15.9	21.2
Glucose (g)	85.7	129	171
Lipids (g)	29.2	43.8	58.4
Glucose : lipid ratio [kcal; % NPE*]	~ 54 : 46		
Osmolarity (mosmol/L) (approx.)	1300/1200†		

* NPE – Non-Protein Energy.
† Values for SmofKabiven Extra Nitrogen Electrolyte Free (per bag).

References

1. SmofKabiven extra Nitrogen. Summary of Product Characteristics. Fresenius Kabi Deutschland GmbH. April 2019.
2. SmofKabiven extra Nitrogen Electrolyte Free. Summary of Product Characteristics. Fresenius Kabi Deutschland GmbH. April 2019.

ESPEN – European Society for Clinical Nutrition and Metabolism.

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3CBs

SmofKabiven® Low Osmo Peripheral[1]

(amino acids + electrolytes, glucose, lipid emulsion)

Prescribing information available on page 20. Always refer to the Summary of Product Characteristics before prescribing.

SmofKabiven Low Osmo Peripheral	6gN	8gN	10gN
Volume	1400ml	1950ml	2500ml
Total energy (kcal)	1000	1400	1800
Amino acids (g)	35.0	48.8	62.6
Nitrogen (g)	5.60	7.81	10.00
Glucose (g)	95.1	132.0	170.0
Lipids (g)	49.0	68.2	87.6
Non-protein calories (kcal)	872	1215	1559
Osmolarity (mOsm/l)	750	750	750
N* : Non-protein energy (g : Kcal)	1 : 156	1 : 156	1 : 156

* N - Nitrogen

Reference

1. SmofKabiven Low Osmo Peripheral. Summary of Product Characteristics. Fresenius Kabi Deutschland GmbH. April 2019.

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Label change

There will be a refreshed label design for our compounding partner ITH's stock bags.

This change will happen with all bags with Addaven* and you will start to see the new labels after the changeover date of June 21st. It may take a few weeks to see the bags in circulation in your hospital.

*Additrace N is licensed in the ROI but is marketed under the brand name Addaven in the UK. Addaven has the same qualitative and quantitative composition as Additrace N and is licensed for the same indications. There are some differences in the summaries of product characteristics; please contact niamh.donnelly@fresenius-kabi.com if you need more information.

CURRENT LABEL

Revised labels include the following features:

The green colour on the top of the label (ITH colour).

The information written in blue is an instruction.

The information written in red indicates a warning.

NEW LABEL

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UPDATE

Compounded bags

The supply of compounded stock bags has improved over the last few months. However, a couple of lines were short this week as we are trying to run down stock to allow for trace element preparation changeover.

Kabi regimens + Addaven* should come into circulation by mid-July. We continue to monitor stock daily but would appreciate if accounts can keep us informed if significant increases or decreases in PN occur in your hospital so we can react accordingly.

To reflect the change in ingredients, the bag name and JPN code will change.

Please see list outlined below:

Bag Name	JPN
Kabi PN 4C + Addaven	JPN92156005
Kabi PN 5C + Addaven	JPN92157005
Kabi PN 6C + Addaven	JPN92152005
Kabi PN 7C + Addaven	JPN92158005
Kabi PN 8C + Addaven	JPN92159005
Kabi PN 10C + Addaven	JPN92160005
Kabi PN 16C + Addaven	JPN92154006
Kabi PN 19C + Addaven	JPN92168005
Kabi PN 20C + Addaven	JPN92155006
Kabi PN 22P + Addaven	JPN92173003
Kabi PN 25C + Addaven	JPN92128005

**For information only:*

Additrace N is licensed in the ROI but is marketed under the brand name Addaven in the UK. A ddaven has the same qualitative and quantitative composition as Additrace N and is licensed for the same indications. There are some differences in the summaries of product characteristics; please contact niamh.donnelly@fresenius-kabi.com if you need more information. Compounded bags in both ROI and NI will be compounded using Addaven from June onwards. The JPN and bag titles have been finalised. They have been sent to each pharmacy departments to ensure your internal systems can be updated. Clanwilliam have been instructed to update the ordering portal.

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HPN survey results[1]

As part of our ongoing commitment to delivering a Homecare service that gives patients the confidence, support and reassurance they need to live with parenteral nutrition at home, we recently ran a survey with our patients and carers to discover how well we are meeting those needs.

References
1. Fresenius Kabi Limited. Data on file. July 2021.

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IrSPEN Satellite Symposium

The IrSPEN Satellite Symposium took place on Tuesday 27th until Wednesday 28th April 2021.

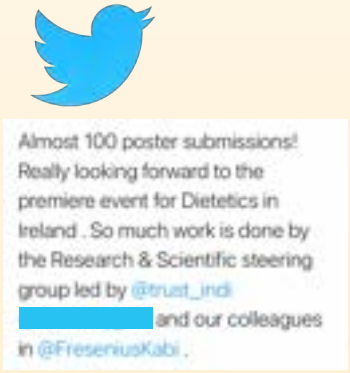
This was the first fully virtual symposium held by IrSPEN and the content will be available up to 6 months after the event. There was a total of 270 delegates who registered for the event as well as just under 100 abstracts submitted.

The IrSPEN committee put together an outstanding programme with leading experts in the field of clinical nutrition, obesity and metabolism, who shared their latest research findings and clinical expertise over these two days. The theme of this year's symposium focused on the need to reposition nutrition as central to healthcare delivery, in which all members of the multidisciplinary team play an important role.

Of the twenty-seven abstracts uploaded to the virtual platform, awards were given to seven dietitians.

These included;

- **Richelle Flanagan** on 'The Unmet Nutritional Needs of People Living with Parkinson's Disease'
- **Erin Stella Sullivan** on the 'High Prevalence of Weight Loss and Abnormal Body Composition in a Large Sample of Ambulatory Irish Cancer Patients'
- **Nicola Dervan** on 'A Nutrition Focused Physical Examination Workship Improves Skills and Knowledge of Dietitians in the Diagnosis of Malnutrition'
- **Aisling Nolan** on 'Evaluating the Nutritional Status of Head and Neck Patients Undergoing Radical Radiotherapy'
- **Laura McBean & Aisling Geraghty** on the 'Analysis of Dispensing Patterns and Non-disease Specific Oral Nutritional Supplement Usage in Primary Care: The ONSPRES Project'
- **Dr. Anne Griffin** on 'The Prevalence and Impact on Patient Outcomes of Malnutrition Among Older Adults Presenting at an Irish Emergency Department: A Secondary Analysis of the Optimend Trial'
- **Dr. Kathryn Allen** on 'The Anorexia Nervosa Care Pathway: Clinical Pathway Compliance Can Standardise Quality of Care for Patients with Severe Anorexia Nervosa Admitted for Medical Monitoring'



At the end of the first day of the conference, the Fresenius Kabi Satellite Symposium took place. The title of this session was 'Patient Experiences and Perspectives in Their Own Words'. Our very own Trisha Nulty welcomed delegates and introduced the speakers involved. First of all, Richelle Flanagan presented on 'Diet & PD: A Dietitian's Perspective of Living with Parkinson's Disease' followed by an interview with Sorcha McElchar and Carolyn Wheatley (Chair of PINNT) going into detail about the trials and tribulations they both face on a daily basis while receiving parenteral nutrition support. Not only this but also highlighting the need for this service and the positive impact it has had on their lives.

This was followed by a live Q&A with Carolyn Wheatley, Richelle Flanagan and Dr Cara Dunne, allowing delegates the opportunity to ask the speakers about their presentations and personal experiences of parenteral nutrition.

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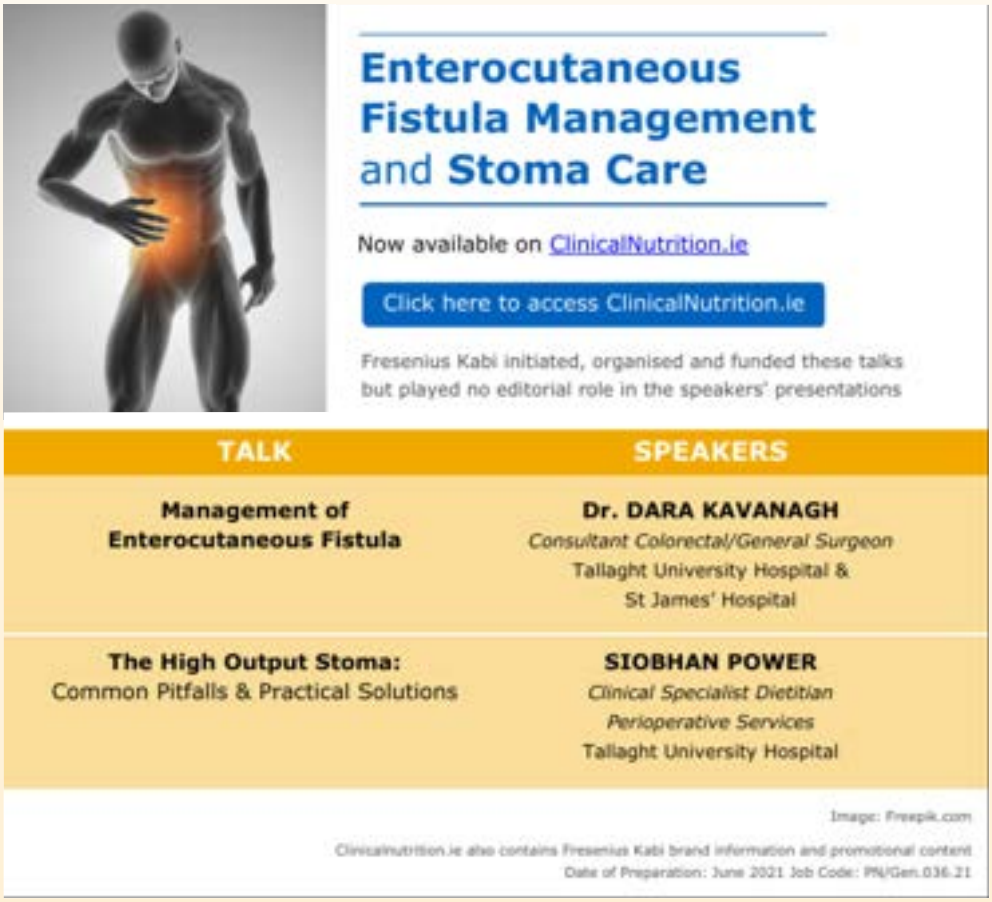
Webinar series

The hospital team are also progressing with the webinar series with our ICU, gastroenterology and dysphagia sessions already available to view on clinicalnutrition.ie.

As well as this, the fourth webinar in the series will focus on surgical which will be accessible from mid-July.

In the upcoming weeks the following articles will be also uploaded to clinicalnutrition.ie:

Topic	Author
The Role of Nutrition in the Prevention & Management of Cancer	**Laura Keaver** Dietitian & Lecturer I.T Sligo
The Role of Vitamin D Status in SARS-CoV-2 Infection and Covid-19 Disease Severity	**Dr. Daniel McCartney** Lecturer in Nutrition & Dietetics TU Dublin



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Fresenius Kabi oncology webcast

The Fresenius Kabi 'Fit for Cancer Surgery – Impact of Prehabilitation' oncology webinar took place on 27th May 2021 and was a wealth of insights and information from speakers across the globe.

Although there was a reduced number of attendees due to the ongoing HSE cyber-attack, it was a very thought-provoking webinar. It is available to view retrospectively on www.nutritionevents.com.

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Mind your mental health webinars

At Fresenius Kabi, we understand the additional strain and workload that has been placed on HCPs' shoulders over the last 12 months, which is why we have commissioned a life coach to run a series of "well-being" webinars, just for you.

The main purpose of the well-being webinars is to look at the four components that impact on what scientists call our AQ, or adversity quotient – guts, resilience, innovation, and tenacity.

The Well-Being (G.R.I.T.) meetings held thus far have proven a very useful and valuable tool giving back to our customers in these challenging times. I'd like to share with you a sample of some of the positive comments received below:

> "I really enjoyed the GRIT meeting as did those I spoke to afterwards."

> "The speaker was great and the content very relevant."

I hope you can take some time out to attend these meetings in the future with key learnings on 'Guts, Resilience, Intensity and Tenacity (G.R.I.T)'.

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Philip's personal note

It's hard to believe that we are halfway through 2021 and what has been another very challenging year for a lot of people. I really hope you have been able to get back to some semblance of normality and that we are all heading in the right direction.

Here at Fresenius Kabi, our products and services are used to help care for critically and chronically ill patients. We have been working tirelessly behind the scenes to ensure that we can continue to provide the highest level of service and products to all our customers across Ireland. Of course, providing high quality nutrition products and support to our customers is at the very heart of our business, it's why we all come to work every day. For me, it's also about giving our customers the products and information to be able to provide the 'best level of care' for their patients in line with our company purpose 'Caring for Life'.

Please don't hesitate to contact me for any service and product inquiries.

Thanks again, your work is appreciated greatly.
Philip

Philip.Doyle@fresenius-kabi.com
086-0143242

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Prescribing information

PRESCRIBING INFORMATION - ADDITRACE® CONCENTRATE FOR SOLUTION FOR INFUSION

Consult the Summary of Product Characteristics for full information. Additional information is available on request.

Active ingredients: Each 1ml of Additrace concentrate contains: Chromic chloride $6H_2O$ 5.33 microgram, Copper chloride $2H_2O$ 340 microgram, Ferric chloride $6H_2O$ 540 microgram, Manganese chloride $4H_2O$ 99 microgram, Potassium iodide 16.6 microgram, Sodium fluoride 210 microgram, Sodium molybdate $2H_2O$ 4.85 microgram, Sodium selenite anhydrous 6.90 microgram, Zinc chloride 1.36 milligram. **Indications:** A source of electrolytes and trace elements as an integral part of complete intravenous regimen for adults and children over 40kg. **Dosage and administration:** Intravenous infusion after dilution. Additrace must not be given undiluted. Recommended dosage for adults: 1 ampoule (10ml) of Additrace is added to a compatible intravenous solution (see SmPC). For infants and children under 40kg, Peditrace® should be used. Dosage is dependent on age, weight and any degree of deficiency of the patient and must be decided on an individual basis. **Contraindications:** Hypersensitivity to the active substances or excipients. **Special warnings and precautions for use:** Care in patients with impaired liver function (especially cholestasis), as manganese toxicity is more likely to occur. Monitor manganese blood levels and liver function monthly in such patients. Stop Additrace if manganese levels rise to the potentially toxic range. Caution in patients with impaired renal function when the excretion of some trace elements (zinc, selenium, fluoride, chromium and molybdenum) may be significantly decreased. Carefully monitor the unborn baby during intravenous administration of parenteral irons to pregnant women; foetal bradycardia can occur. **Undesirable effects:** There have been no reported undesirable effects observed during the administration of Additrace. Other adverse reactions can occur, see SmPC for details. **Legal Category:** POM **Marketing Authorisation Holder:** Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. **Marketing Authorisation Number:** PA 2059/023/001 **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** November 2020 API/Additrace-01.

PRESCRIBING INFORMATION - ADDITRACE® N CONCENTRATE FOR SOLUTION FOR INFUSION

Consult the Summary of Product Characteristics for full information. Additional information is available on request.

Active ingredients: Each 10ml ampoule of Additrace N contains: Chromic chloride hexahydrate 53.3 microgram, Copper chloride dihydrate 1.02 milligram, Ferric chloride hexahydrate 5.40 milligram, Manganese chloride tetrahydrate 198 microgram, Potassium iodide 166 microgram, Sodium fluoride 2.10 milligram, Sodium molybdate dihydrate 48.5 microgram, Sodium selenite anhydrous 173 microgram, Zinc chloride 10.5 milligram. **Indications:** To meet basal to moderately increased requirements of trace elements in intravenous nutrition. **Dosage and administration:** Additrace N must not be given undiluted; only add to medicinal or nutritional solutions for which compatibility has been documented. Recommended daily dosage for adults with basal to moderately increased requirements: 1 ampoule (10ml). Additrace N is not recommended for use in children weighing under 40kg body weight; Peditrace® should be used. Dosage is dependent on age, weight and any degree of deficiency of the patient and must be decided on an individual basis. **Contraindications:** Hypersensitivity to the active substances or any of the excipients, conditions with total biliary obstruction, Wilson's disease. **Special warnings and precautions for use:** Use with caution in patients with impaired biliary and/or renal function in whom the excretion of trace elements (zinc, selenium, fluoride, chromium and molybdenum) may be significantly decreased, and in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis). Check manganese blood levels if treatment continued for more than 4 weeks. Stop Additrace N if manganese levels rise to the potentially toxic range (refer to appropriate reference ranges of the testing laboratory). Carefully monitor the unborn baby during intravenous administration of parenteral irons to pregnant women; foetal bradycardia can occur. **Undesirable effects:** No adverse effects related to the trace elements in Additrace N have been reported. Other adverse reactions can occur, see SmPC for details. **Legal Category:** POM **Marketing Authorisation Holder:** Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. **Marketing Authorisation Number:** PA 2059/023/002 **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** December 2020 API/AdditraceN-01

Adverse events should be reported.
Reporting forms and information can be found at:
www.hpra.ie/homepage/about-us/report-an-issue
Adverse events should also be reported to Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT Tel +44 (0)1928 533 533.

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PRESCRIBING INFORMATION – SMOFKABIVEN® EXTRA NITROGEN, EMULSION FOR INFUSION.

Consult the Summary of Product Characteristics for full information. Additional information is available on request.

Active ingredients: 2025ml bag Amino acid solution 10% with electrolytes 1325ml, Glucose 42% 408ml, Lipid emulsion 20% 292ml – corresponding to: Soya-bean oil (refined) 18g, Medium-chain triglycerides 18g, Olive oil (refined) 15g, Fish oil (rich in omega-3-acids) 8.8g, Glucose (monohydrate) 171g, Alanine 19g, Arginine 16g, Glycine 15g, Histidine 4.0g, Isoleucine 6.6g, Leucine 9.8g, Lysine (as acetate) 8.7g, Methionine 5.7g, Phenylalanine 6.8g, Proline 15g, Serine 8.6g, Taurine 1.3g, Threonine 5.8g, Tryptophan 2.7g, Tyrosine 0.53g, Valine 8.2g, Calcium chloride (as dihydrate) 0.58g, Sodium glycerophosphate (as hydrate) 4.6g, Magnesium sulphate (as heptahydrate) 1.2g, Potassium chloride 4.6g, Sodium acetate (as trihydrate) 3.3g, Zinc sulphate (as heptahydrate) 0.013g ***1518ml bag*** Amino acid solution 10% with electrolytes 993ml, Glucose 42% 306ml, Lipid emulsion 20% 219ml – corresponding to: Soya-bean oil (refined) 13g, Medium-chain triglycerides 13g, Olive oil (refined) 11g, Fish oil (rich in omega-3-acids) 6.6g, Glucose (monohydrate) 129g, Alanine 14g, Arginine 12g, Glycine 11g, Histidine 3.0g, Isoleucine 5.0g, Leucine 7.3g, Lysine (as acetate) 6.6g, Methionine 4.3g, Phenylalanine 5.1g, Proline 11g, Serine 6.5g, Taurine 1.0g, Threonine 4.4g, Tryptophan 2.0g, Tyrosine 0.40g, Valine 6.2g, Calcium chloride (as dihydrate) 0.43g, Sodium glycerophosphate (as hydrate) 3.5g, Magnesium sulphate (as heptahydrate) 0.92g, Potassium chloride 3.5g, Sodium acetate (as trihydrate) 2.5g, Zinc sulphate (as heptahydrate) 0.010g ***1012ml bag*** Amino acid solution 10% with electrolytes 662ml, Glucose 42% 204ml, Lipid emulsion 20% 146ml – corresponding to: Soya-bean oil (refined) 8.8g, Medium-chain triglycerides 8.8g, Olive oil (refined) 7.3g, Fish oil (rich in omega-3-acids) 4.4g, Glucose (monohydrate) 86g, Alanine 9.3g, Arginine 7.9g, Glycine 7.3g, Histidine 2.0g, Isoleucine 3.3g, Leucine 4.9g, Lysine (as acetate) 4.4g, Methionine 2.8g, Phenylalanine 3.4g, Proline 7.4g, Serine 4.3g, Taurine 0.66g, Threonine 2.9g, Tryptophan 1.3g, Tyrosine 0.26g, Valine 4.1g, Calcium chloride (as dihydrate) 0.29g, Sodium glycerophosphate (as hydrate) 2.3g, Magnesium sulphate (as heptahydrate) 0.62g, Potassium chloride 2.3g, Sodium acetate (as trihydrate) 1.6g, Zinc sulphate (as heptahydrate) 0.0066g **Indications:** Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration:** Intravenous infusion into a central vein. The dose should be individualised to the patient's clinical condition, body weight (bw) and nutritional requirements. Adults – Dosage range of 13-31ml/kg bw/day covers the needs of the majority of patients. In obese patients dose should be based on estimated ideal weight. The recommended maximum daily dose is 31ml/kg bw/day. Adult infusion rate should not exceed 1.5ml/kg bw/hour (corresponding to 0.13g glucose, 0.10g amino acids, and 0.04g lipids/kg bw/hour). The recommended infusion period is 14-24 hours. Children (2-11 years) - the recommended maximum infusion rate is 1.8ml/kg bw/hour (corresponding to 0.15g glucose, 0.12g amino acids, and 0.05g lipids/kg/hour). Maximum daily dose is 31ml/kg bw/day. The recommended infusion period is 12-24 hours. At the maximum infusion rate, do not use an infusion period longer than 17 hours, except in exceptional cases and with careful monitoring. Adolescents (12-16/18 years) – Use as in adults. To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes should be added according to the patient's need (check compatibility). **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, congenital errors of amino acid metabolism, severe renal insufficiency without access to hemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, pathologically elevated serum levels of any of the included electrolytes, general contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency; hemophagocytotic syndrome, unstable conditions, neonates and infants under 2 years of age. **Special warnings and precautions for use:** The patient's ability to eliminate lipid should be monitored by checking triglyceride levels. Serum triglyceride concentration should not exceed 4 mmol/l during infusion. Disturbances of electrolyte and fluid balance should be corrected before starting the infusion. Special clinical monitoring is required at the beginning of any intravenous infusion and should any abnormal sign occur, the infusion must be stopped. Strict aseptic precautions should be taken. Use a continuous and well controlled infusion. Use with caution in conditions of impaired lipid metabolism. Monitor serum glucose, electrolytes, osmolarity, fluid balance, acid-base status, liver enzyme tests. Blood cell count and coagulation should be monitored when lipids are given for a longer period. Use with caution in lactic acidosis, insufficient cellular oxygen supply, increased serum osmolarity, in patients with a tendency to electrolyte retention, in malnourished patients (careful and slow initiation recommended with close monitoring and appropriate dose adjustments) and patients with renal insufficiency (carefully control phosphate and potassium intake). Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to the immediate interruption of the infusion. Contains soya-bean oil, fish oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Electrolyte additions should be governed by patient's clinical condition and frequent monitoring. Consider trace element dosing, especially during long-term administration. Lipid content may interfere with laboratory measurements if blood sampled before lipid is cleared from bloodstream. Do not administer with blood in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. Not suitable for use in newborns or infants below 2 years of age. No clinical experience in children and adolescents age 2 years to 16/18 years. **Undesirable effects:** *Common* - slight increase in body temperature. *Uncommon* - nausea, vomiting, lack of appetite, headache, elevated plasma levels of liver enzymes, chills, dizziness. *Rare* – tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Other adverse reactions can occur (including fat overload syndrome) see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Number:** UK: PL 08828/0268, IE: PA 2059/060/001. **Marketing Authorisation Holder:** UK: Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. IE: Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.H. 61352, Germany. **Package Size and Cost:** 2025ml £89.00, 1518ml £80.00, 1012ml £75.00. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** February 2021 API/SKEN-01

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If you would rather not receive this bimonthly newsletter from Fresenius Kabi please let your local hospital representative know.

PRESCRIBING INFORMATION – SMOFKABIVEN® EXTRA NITROGEN ELECTROLYTE FREE, EMULSION FOR INFUSION.

Consult the Summary of Product Characteristics for full information. Additional information is available on request.

Active ingredients: ***2025ml bag*** Amino acid solution 10% 1325ml, Glucose 42% 408ml, Lipid emulsion 20% 292ml – corresponding to: Soya-bean oil (refined) 18g, Medium-chain triglycerides 18g, Olive oil (refined) 15g, Fish oil (rich in omega-3-acids) 8.8g, Glucose (monohydrate) 171g, Alanine 19g, Arginine 16g, Glycine 15g, Histidine 4.0g, Isoleucine 6.6g, Leucine 9.8g, Lysine (as acetate) 8.7g, Methionine 5.7g, Phenylalanine 6.8g, Proline 15g, Serine 8.6g, Taurine 1.3g, Threonine 5.8g, Tryptophan 2.7g, Tyrosine 0.53g, Valine 8.2g ***1518ml bag*** Amino acid solution 10% 993ml, Glucose 42% 306ml, Lipid emulsion 20% 219ml – corresponding to: Soya-bean oil (refined) 13g, Medium-chain triglycerides 13g, Olive oil (refined) 11g, Fish oil (rich in omega-3-acids) 6.6g, Glucose (monohydrate) 129g, Alanine 14g, Arginine 12g, Glycine 11g, Histidine 3.0g, Isoleucine 5.0g, Leucine 7.3g, Lysine (as acetate) 6.6g, Methionine 4.3g, Phenylalanine 5.1g, Proline 11g, Serine 6.5g, Taurine 1.0g, Threonine 4.4g, Tryptophan 2.0g, Tyrosine 0.40g, Valine 6.2g ***1012ml bag*** Amino acid solution 10% 662ml, Glucose 42% 204ml, Lipid emulsion 20% 146ml – corresponding to: Soya-bean oil (refined) 8.8g, Medium-chain triglycerides 8.8g, Olive oil (refined) 7.3g, Fish oil (rich in omega-3-acids) 4.4g, Glucose (monohydrate) 86g, Alanine 9.3g, Arginine 7.9g, Glycine 7.3g, Histidine 2.0g, Isoleucine 3.3g, Leucine 4.9g, Lysine (as acetate) 4.4g, Methionine 2.8g, Phenylalanine 3.4g, Proline 7.4g, Serine 4.3g, Taurine 0.66g, Threonine 2.9g, Tryptophan 1.3g, Tyrosine 0.26g, Valine 4.1g **Indications:** Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration:** Intravenous infusion into a central vein. The dose should be individualised to the patient's clinical condition, body weight (bw) and nutritional requirements. *Adults* – Dosage range of 13-31ml/kg bw/day covers the needs of the majority of patients. In obese patients dose should be based on estimated ideal weight. The recommended maximum daily dose is 31ml/kg bw/day. Adult infusion rate should not exceed 1.5ml/kg bw/hour (corresponding to 0.13g glucose, 0.10g amino acids, and 0.04g lipids/kg bw/hour). The recommended infusion period is 14-24 hours. *Children (2-11 years)* - the recommended maximum infusion rate is 1.8ml/kg bw/hour (corresponding to 0.15g glucose, 0.12g amino acids, and 0.05g lipids/kg/hour). Maximum daily dose is 31ml/kg bw/day. The recommended infusion period is 12-24 hours. At the maximum infusion rate, do not use an infusion period longer than 17 hours, except in exceptional cases and with careful monitoring. *Adolescents (12-16/18 years)* – Use as in adults. To provide total parenteral nutrition, trace elements, vitamins and electrolytes should be added according to the patient's need (check compatibility). **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, congenital errors of amino acid metabolism, severe renal insufficiency without access to hemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, general contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency; hemophagocytotic syndrome, unstable conditions, neonates and infants under 2 years of age. **Special warnings and precautions for use:** The patient's ability to eliminate lipid should be monitored by checking triglyceride levels. Serum triglyceride concentration should not exceed 4 mmol/l during infusion. Strict aseptic precautions should be taken. Use a continuous and well controlled infusion. Use with caution in conditions of impaired lipid metabolism. Monitor serum glucose, electrolytes, osmolarity, fluid balance, acid-base status, liver enzyme tests. Blood cell count and coagulation should be monitored when lipids are given for a longer period. Use with caution in lactic acidosis, insufficient cellular oxygen supply, increased serum osmolarity, in malnourished patients (careful and slow initiation recommended with close monitoring and appropriate dose adjustments) and patients with renal insufficiency (carefully control phosphate and potassium intake). Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to the immediate interruption of the infusion. Contains soya-bean oil, fish oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Electrolyte additions should be governed by patient's clinical condition and frequent monitoring. Consider trace element dosing, especially during long-term administration. Lipid content may interfere with laboratory measurements if blood sampled before lipid is cleared from bloodstream. Do not administer with blood in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. Not suitable for use in newborns or infants below 2 years of age. No clinical experience in children and adolescents age 2 years to 16/18 years. **Undesirable effects:** *Common* - slight increase in body temperature. *Uncommon* - nausea, vomiting, lack of appetite, headache, elevated plasma levels of liver enzymes, chills, dizziness. *Rare* – tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM. **Marketing Authorisation Number: UK:** PL 08828/0269, IE: PA 2059/060/002. ***Marketing Authorisation Holder:*** UK: Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, UK. IE: Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.H. 61352, Germany. **Package Size and Cost:** 2025ml £89.00, 1518ml £80.00, 1012ml £75.00. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** February 2021 API/SKEN-EF-01

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PRESCRIBING INFORMATION - SMOFKABIVEN® LOW OSMO PERIPHERAL EMULSION FOR INFUSION.

Consult the Summary of Product Characteristics for full information. Additional information is available on request.

Active ingredients: 2500ml bag Amino acid solution 10% with electrolytes 625ml, Glucose 11.8% 1438ml, Lipid emulsion 20% 438ml – corresponding to: Soya-bean oil (refined) 26g, Medium-chain triglycerides 26g, Olive oil (refined) 22g, Fish oil (rich in omega-3-acids) 13g, Glucose (as monohydrate) 170g, Alanine 8.8g, Arginine 7.5g, Glycine 6.9g, Histidine 1.9g, Isoleucine 3.1g, Leucine 4.6g, Lysine (as acetate) 4.1g, Methionine 2.7g, Phenylalanine 3.2g, Proline 7.0g, Serine 4.1g, Taurine 0.63g, Threonine 2.8g, Tryptophan 1.3g, Tyrosine 0.25g, Valine 3.9g, Calcium chloride (as dihydrate) 0.35g, Sodium glycerophosphate (as hydrate) 2.6g, Magnesium sulphate (as heptahydrate) 0.75g, Potassium chloride 2.8g, Sodium acetate (as trihydrate) 2.1g, Zinc sulphate (as heptahydrate) 0.0081g **1950ml bag** Amino acid solution 10% with electrolytes 488ml, Glucose 11.8% 1121ml, Lipid emulsion 20% 341ml – corresponding to: Soya-bean oil (refined) 20g, Medium-chain triglycerides 20g, Olive oil (refined) 17g, Fish oil (rich in omega-3-acids) 10g, Glucose (as monohydrate) 130g, Alanine 6.8g, Arginine 5.9g, Glycine 5.4g, Histidine 1.5g, Isoleucine 2.4g, Leucine 3.6g, Lysine (as acetate) 3.2g, Methionine 2.1g, Phenylalanine 2.5g, Proline 5.5g, Serine 3.2g, Taurine 0.49g, Threonine 2.1g, Tryptophan 0.98g, Tyrosine 0.20g, Valine 3.0g, Calcium chloride (as dihydrate) 0.27g, Sodium glycerophosphate (as hydrate) 2.0g, Magnesium sulphate (as heptahydrate) 0.59g, Potassium chloride 2.2g, Sodium acetate (as trihydrate) 1.7g, Zinc sulphate (as heptahydrate) 0.0063g **1400ml bag** Amino acid solution 10% with electrolytes 350ml, Glucose 11.8% 805ml, Lipid emulsion 20% 245ml – corresponding to: Soya-bean oil (refined) 15g, Medium-chain triglycerides 15g, Olive oil (refined) 12g, Fish oil (rich in omega-3-acids) 7.4g, Glucose (as monohydrate) 95g, Alanine 4.9g, Arginine 4.2g, Glycine 3.9g, Histidine 1.1g, Isoleucine 1.8g, Leucine 2.6g, Lysine (as acetate) 2.3g, Methionine 1.5g, Phenylalanine 1.8g, Proline 3.9g, Serine 2.3g, Taurine 0.35g, Threonine 1.5g, Tryptophan 0.7g, Tyrosine 0.14g, Valine 2.2g, Calcium chloride (as dihydrate) 0.20g, Sodium glycerophosphate (as hydrate) 1.5g, Magnesium sulphate (as heptahydrate) 0.42g, Potassium chloride 1.6g, Sodium acetate (as trihydrate)1.2g, Zinc sulphate (as heptahydrate) 0.0045g **Indications:** Parenteral nutrition for adults and children aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. **Dosage and administration:** Intravenous infusion into a central or peripheral vein. The dose should be individualised to the patient's clinical condition, body weight (bw), nutritional and energy requirements. *Adults* - The dose range of 20-40 ml/kg bw/day covers the needs of the majority of patients. In obese patients the dose should be based on the estimated ideal weight. The recommended maximum daily dose is 40 ml/kg bw/day. Infusion rate should not exceed 3.7 ml/kg bw/hour (corresponding to 0.25 g glucose, 0.09 g amino acids, and 0.13 g lipids/kg bw/hour). The recommended infusion period for adults is 12-24 hours. *Children (2-11 years)* - The infusion rate should not exceed 4.0 ml/kg bw/hour (corresponding to 0.27 g glucose, 0.10 g amino acids and 0.14 g lipids/kg/hour). At the maximum infusion rate, do not use an infusion period of longer than 10 hours, except in exceptional circumstances with careful monitoring. The recommended infusion period in children aged 2-11 is 12-24 hours. The recommended maximum daily dose is 40 ml/kg bw/day. *Adolescents* - SmofKabiven Low Osmo Peripheral can be used as in adults. To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes should be added according to the patient's need. **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, congenital errors of amino acid metabolism, severe renal insufficiency without access to haemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, pathologically elevated serum levels of any of the included electrolytes, general contraindications to infusion therapy (acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency), haemophagocytotic syndrome, unstable conditions, neonates and infants under 2 years of age. **Special warnings and precautions for use:** See SmPC for further information. Use with caution in conditions of impaired lipid metabolism, in patients with a tendency towards electrolyte retention, in lactic acidosis, increased serum osmolarity and insufficient cellular oxygen supply. Contains soya-bean oil, fish oil and egg phospholipids which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut. Use a continuous and well-controlled infusion. Strict aseptic precautions should be taken. Electrolyte and fluid balance disturbances should be corrected prior to infusion. Special clinical monitoring is required at the beginning of any infusion and should any abnormal sign occur (including anaphylactic reaction), the infusion must be stopped. Carefully control phosphate and potassium intake in patients with renal insufficiency. Monitor triglyceride levels (serum concentration should not exceed 4 mmol/l during infusion), serum glucose, electrolytes, osmolarity, fluid balance, acid-base status and liver enzyme tests. When lipids are given for a longer period, monitor blood cell count and coagulation. Lipid content may interfere with certain laboratory measurements if blood sampled before lipid clearance. Consider trace element dosing as intravenous infusion of amino acids is accompanied by increased urinary excretion of trace elements, in particular copper and zinc. Careful and slow initiation is recommended in malnourished patients with close monitoring and appropriate dose adjustments. Do not administer with blood in the same infusion set. Exogenous insulin may be necessary in patients with hyperglycaemia. Thrombophlebitis may occur if peripheral veins used for infusion. No clinical experience in children (aged 2 to 16/18 years). **Undesirable effects:** Common – Slight increase in body temperature, within a few days vein irritation, phlebitis or thrombophlebitis. Uncommon – Lack of appetite, nausea, vomiting, elevated plasma levels of liver enzymes, chills, dizziness, headache. Rare – Tachycardia, dyspnoea, hypotension, hypertension, hypersensitivity reactions, heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins. Other adverse reactions can occur (including fat overload syndrome), see SmPC for details. **Legal Category:** POM **Marketing Authorisation Number:** UK: PL 08828/0274. IE: PA 2059/022/001. **Marketing Authorisation Holder:** UK - Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT, UK. IE – Fresenius Kabi Deutschland GmbH, Else-Kroener Strasse 1, Bad Homburg v.d.h. 61352, Germany. **Package Size and Cost:** 2500ml £68.00, 1950ml £61.00, 1400ml £58.00. **Further information:** Available from Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT. Tel +44 (0)1928 533 533. **Date of preparation:** October 2020 API/LowOsmo-01

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