

CLINICAL NUTRITION

# UPDATE

From **Fresenius Kabi**

**In this issue:**

**Parenteral nutrition**

**Home parenteral nutrition**

**Educational opportunities**

**Volume 2** May 2021



 **FRESENIUS  
KABI**  
caring for life

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

# WELCOME

Welcome to the second edition of the Fresenius Kabi PN (parenteral nutrition) Service Update. This will be circulated every 8 weeks with relevant updates to our service as well as a recurring 'Introducing' article to allow you to familiarise yourselves with the Fresenius Kabi PN team and put some faces to names. 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.

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](mailto:megan.hearty@fresenius-kabi.com).

## CONTENTS

### Introducing

- 3 Olive
- 4 Trisha

### Parenteral Nutrition

- 5 Compounded bag supply
- 6 Active cold chain
- 7 Additrace®  
(iron, zinc, manganese, copper, chromium, selenium, molybdenum, fluoride, iodine)  
Additrace N®  
(chromium, copper, iron, manganese, iodine, fluoride, molybdenum, selenium, zinc)
- 9 3CB label change update

### HPN

- 10 Survey
- 10 Fair Processing Notice

### Education

- 11 INDI/Fresenius Kabi research symposium
- 12 Webinar series
- 13 Save the dates
  - IrSPEN satellite symposium
  - Oncology webinar
- 15 Mind your mental health workshops



# Team members

Introducing...

## Olive Nolan

Homecare Specialist and  
Hospital Sales Representative



Hi, my name is Olive and I am in my 20<sup>th</sup> year with Fresenius Kabi, having joined in January 2001. I am a Dietitian and I graduated from Kevin Street DIT in 1998. I worked as a Dietitian until I joined Fresenius Kabi, my last role as a Senior Dietitian in Children's Health Ireland, CHI at Crumlin.

I have had many roles within Fresenius Kabi in sales, product management, nutrition services and Homecare. It is often joked about internally that I have done every job at this stage! The company has grown massively in Ireland since I joined all those years ago and I am lucky to still work with colleagues who joined around the same time as me. Those relationships and friendships have been very important to me over the years.

I am currently working as a Homecare Specialist and Hospital Sales Representative. Having worked as the Homecare Manager for several years this area is close to my heart.

I like learning new skills and I certainly have done that over the years. I completed a MSc in Pharmaceutical Regulatory Affairs in 2018 and I really enjoyed getting back to learning.

Away from work I do a lot of volunteer work in the local community and anyone that knows me knows I am passionate about Community Games and athletics and I have been involved in our local area/club in Carlow for many years. Our area won the Best Area in Leinster in 2019 and personally this was a great achievement for me. I am also in the local choir and I am missing all the activities and singing at the moment. I'm married to Ed and have three children - Ruth who is in third year, Edward is in first year and the youngest John is in 2<sup>nd</sup> class so lots of home-schooling now!

# Team members

## Introducing... **Trisha Nulty**

Hospital Sales Manager for  
Parenteral and Enteral Nutrition



Hi, my name is Trisha and I joined Fresenius Kabi in 1999 just after it was set up here in Ireland. I left the business for around a year for childcare reasons and re-joined again 8 years ago. I qualified as a nurse in 1991 and as midwife in 1994. I love the hospital environment.

I have had several roles within Fresenius Kabi; I started out as a sales representative for Northern Ireland, then field sales manager and now hospital sales manager for Parenteral and Enteral nutrition across all of Ireland. When I first started there were only 4 employees across the whole business; Fresenius Kabi has grown and expanded hugely since then. I have worked with some of the same people for the past 20 years and it is wonderful to have them as colleagues, but also as friends and to have seen engagements, weddings, babies and grandchildren over the years.

I like to learn new skills and 2 years ago I became an Insights Practitioner, this is about understanding personality preferences and behaviours. I am also a qualified executive coach.

Outside of work I am chairperson of our local swimming club and child officer of the gymnastics club. I spend many weekends at the side of a pool and the gymnastics team have keep me busy as we have travelled to Norway, Italy, Switzerland and Austria and we are hoping to go to Lisbon this year for another event - Gym for Life. I also am back doing a bit of running but it's hard work, especially in the winter.

I'm married to Kilian and have 4 children (well they are still children to me); Oran is 22, Cara is 20, Molly is 16 and Aisling is 13.

# Compounded bag supply

**Fresenius Kabi are now able to offer stock bags to all hospitals throughout Ireland.**

To maximise efficient use of compounding capacity and to minimise wastage, the number of bags available have been reviewed and rationalised.

The bags now available are:  
Kabi 4C, 5C, 6C, 7C, 8C, 10C,  
11C, 12C, 16C, 19C, 20C & 22P.

This is a temporary list and we envisage it will be revised once the formulation review is completed.



# Active cold chain

**Both HPN and Dublin hospital deliveries will transition next month to being transported end-to-end (collection from compounding unit to hospital/home) in refrigerated vehicles where the parenteral nutrition (PN) will be held between 2°C and 8°C.**

This arrangement aims to provide additional protection and increased flexibility should there be any requirement to store the PN in the vehicle for longer periods of time. The PN will be delivered in plain boxes which will replace polystyrene boxes and ice brick inserts.

Your local representative will be in close contact over the coming weeks to discuss moving to cold chain and estimate usage as we are aware usage remains variable due to Covid-19.



# Additrace

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

# Additrace N

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

## Fresenius Kabi are launching a multi-trace element preparation called Additrace N.

**This 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.<sup>1</sup>**

The table below outlines the differences between Additrace and Additrace N. Prescribing information available on page 17.

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

Comparative admixing studies have been performed between Additrace and Additrace N. Results showed no difference between the two products and equivalent compatibility can be concluded.<sup>4</sup>

Additrace N is indicated to meet basal to moderately increased requirements of trace elements in intravenous nutrition in adults, and children weighing at least 40kg bodyweight.

From week commencing 7th June, all Kabi regimens manufactured will contain Addaven\* rather than Additrace. Comparative admixing studies have been performed between Additrace and Addaven. Results showed no difference between the two products and equivalent compatibility can be concluded.<sup>4</sup>

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. 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](mailto: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. New JPN and bag titles are currently being finalised. This will be sent to each pharmacy department as soon as possible to ensure your internal systems can be updated. Clanwilliam will be instructed to update the ordering portal.*

**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
4. Fresenius Kabi Internal Data 2021.

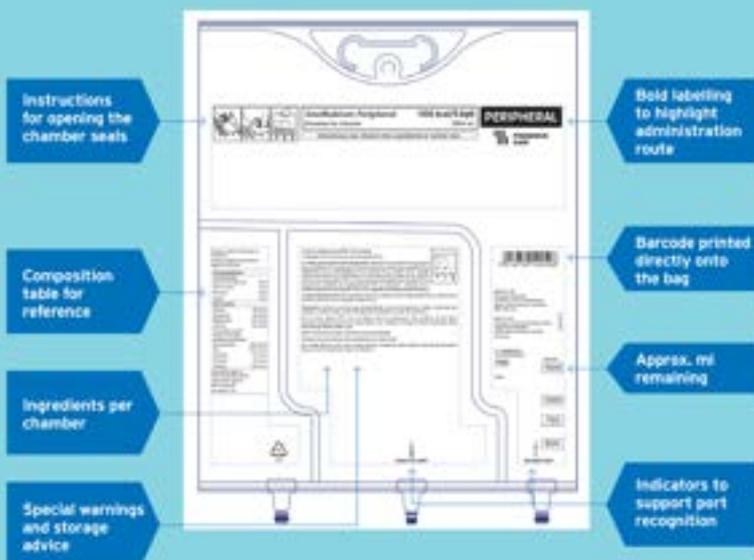
# 3CB label change update

As mentioned in the previous newsletter, there has been a label change on our 3CB products. Below is a reminder of the changes you can expect to see on our new labels.

## Safety and convenience are our priority

The redesigned labels aim to support:

- Identification of the correct bag
- Differentiation of bags for central and peripheral administration routes



The redesigned labels will be implemented in a phased approach throughout our 3-chamber bag range

The roll out has been extended and involves:

- SmofKabiven® Central (amino acids, electrolytes, glucose, lipid emulsion)
- SmofKabiven® Electrolyte Free Central (amino acids, glucose, lipid emulsion)
- SmofKabiven Peripheral (amino acids, electrolytes, glucose, lipid emulsion)

Ordering codes	
831901220	SmofKabiven 8
831905220	SmofKabiven EF 8
831902220	SmofKabiven 12
831906220	SmofKabiven EF 12
831912220	SmofKabiven Peripheral 9.8gN

Prescribing information can be found at the end of this newsletter.

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

# Home Parenteral Nutrition (HPN)

## Survey

The HPN patient satisfaction survey was sent to all patients in ROI (Republic of Ireland) this month and the response rate to date has been very good. The results will be published in the next edition of the newsletter.

## Fair Processing Notice

An update on our Fair Processing Notice (information on how personal data is handled within Fresenius Kabi) was also sent to all patients. Further information on this can be found at:

[Click here to read our Fair Processing Notice](#)

# INDI/Fresenius Kabi research symposium

**The INDI and Fresenius Kabi research conference took place on 4th March 2021. This was the 6th conference of its kind but the first to go fully online due to the Covid-19 pandemic.**

Niamh Furey welcomed the delegates, and we celebrated the growth and breadth of research now taking place in Dietetics in Ireland. This was highlighted by Niamh on the night reporting that the first such conference had 33 delegates 6 years ago, with our 2021 conference having a staggering 529 delegates and 90 research posters!

Of the 90 research posters, there were three which were short-listed to be presented in the first session of the night called 'Research-in-Three'. In this section, Sarah Browne from UCD showcased her qualitative study on community healthcare professionals' and patients' opinions on the term 'malnutrition', titled 'Don't go near the word malnutrition'. Following this, 'A Clinical Audit. Implementation of Nasogastric Feeding in a CAMHS inpatient setting: one year on.' was presented by Nicole Barrett who is a specialist Dietitian in Linn Dara Approved Centre. Finally, Rebecca Whyte, a dietitian in Midland Regional Hospital Mullingar presented her research on 'An Exploration of the Association between Nutrition and Depression and Anxiety Levels in Post-Primary Students in Ireland.'

Afterwards, the presenters answered questions from the audience in a live Q&A session and the viewers had the opportunity to vote on a poll as to which was their favourite presentation.

In the next session of the night, three nominees for the INDI Dietitian of the Year presented their research. Laura Keaver from I.T Sligo gave insight into 'Nutrition in cancer survivorship in Ireland' followed by Cathy Breen's presentation on 'Evidence based dietary management of diabetes and obesity'. Finally Fiona Byrne presented her research on 'The evidence base for a modified low phosphorus diet in Chronic Kidney Disease'. During the interval, there was a 'Chair Yoga' session to allow the viewers to have a break and stretch out after taking in all the information from all the presentations.

Following this, there were presentations from Daniel McCartney from TU Dublin on SARS-CoV-2 infection and Vitamin D, and Eimear Forbes on the development of the 'Ketogenic Diet Therapy Online Education Programme' as well as Barbara Gillman, who presented on behalf of the INDI RIG on the development of renal education and resources for Irish dietitians in the Research Quality Improvement in Dietetic Practice 2021 section of the symposium.

Finally, the awards were presented to the winners of each session, who were Rebecca Whyte, Laura Keaver and Daniel McCartney.

## The INDI conference was trending in Ireland on twitter on the night - a celebration to the success of the event!



Wow 500 registered... 100 posters and a great line up of speakers for this evening! Well done @trust\_indi and all involved in organization of online event, what a great platform @trust\_indi for sharing and recognising dietetic research. #INDIResearch2021

Really excited for tonight! In what has been the most challenging year, dietitians have still managed to produce top quality research to further our profession & tonight we celebrate it. Fingers crossed my broadband gets fixed in time to enjoy it to the fullest! #indiiresearch2021

Missing the in-person events of previous years but I have loved being able to dip in and out of the posters all day as well as the presentations this evening. Well done to all the organisers!

@trust\_indi #INDIResearch2021

# Webinar series

## Our free Digital Learning Webinar Series went live at the beginning of March.

The first therapeutic area was covered in ICU (Intensive Care Unit). The second webinar covering Gastroenterology was streaming every lunchtime until 23rd April.

For those who missed the opportunity to dial in live, the video will be hosted on [clinicalnutrition.ie](http://clinicalnutrition.ie) throughout the week commencing 10th May along with a new article on food sustainability.

### Gastroenterology webinar

Topic	Speaker
<b>Intestinal Rehab and building a new service, one year on</b>	<b>Dr. Cara Dunne</b> Consultant Gastroenterologist St. James's Hospital
<b>Update on Home PN Service in Cork University Hospital</b>	<b>Ellen O'Mahony</b> Senior Dietitian Cork University Hospital
<b>An update on Eosinophilic Oesophagitis</b>	<b>Dr. Inder Mainie</b> Gastroenterology Consultant Belfast City Hospital, Belfast Trust

### ICU webinar

Topic	Speaker
<b>Lessons learned in the pandemic: ICU Nutritional Support</b>	<b>Ms. Carmel O'Hanlon</b> ICU Dietitian Beaumont Hospital, Dublin
<b>Acute Respiratory Distress Syndrome (ARDS)</b>	<b>Dr. Tharwat Aisa</b> Anaesthetic Registrar Our Lady of Lourdes Hospital, Drogheda, County Louth
<b>Nutritional Composition of PN</b>	<b>Marie Sheahan</b> Senior ICU Dietitian Cork University Hospital

# Save the dates

## IrSPEN Satellite Symposium

A promotional graphic for the Fresenius Kabi Satellite Symposium. It features the Fresenius Kabi logo (three vertical bars) and the tagline 'caring for life'. The main title is 'Fresenius Kabi Satellite Symposium "Patient Experiences and Perspectives: In their own words"'. Below this, it states 'IrSPEN 2021 Virtual Conference on 27th of April at 3:30PM'. A dark blue button with white text says 'REGISTER HERE TO ACCESS THE WEBINAR'. At the bottom left, there is a disclaimer: 'This symposium is sponsored by Fresenius Kabi Limited. The content has been initiated by Fresenius Kabi with input from patients managed on home parenteral nutrition in Ireland and input also from a dietetic speaker.' At the bottom right, there is the IrSPEN logo (Irish Society for Parenteral Nutrition & Metabolism) and a partial image of a person's face in profile, looking down, with blue and green brushstrokes.

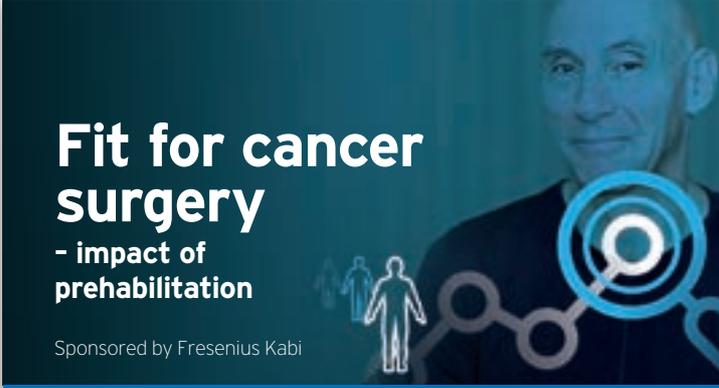
The IrSPEN 2021 Virtual Conference is now available online for the next 6 months.

### Sessions included:

- **Richelle Flanagan**  
RD & PD Advocate: *A Dietitian's perspective of living with PD*
- **Sorcha McElchar**  
HPN Patient: *My personal experience of Home Parenteral Nutrition*
- **Live Q&A with:**  
Carolyn Wheatley, *Chair of PINNT (Patients on Intravenous and Naso-gastric Nutrition Therapy)*, Richelle Flanagan, *RD & PD Advocate, Be Nutrition Wise*, and Dr Cara Dunne, *Consultant Gastroenterologist, St James's Hospital*

# Save the dates

## Oncology webinar



### Fit for cancer surgery - impact of prehabilitation

Sponsored by Fresenius Kabi

Join the FREE live webcast with 2 live sessions on:  
**Thursday May 27, 2021** 8AM & 4PM IST

Learn more about this event available only on:  
[nutritionevents.com](https://www.nutritionevents.com)



**FRESENIUS KABI**  
caring for life

### Fit for cancer surgery - impact of prehabilitation

**Webcast program**

**Join the live webcast**  
May 27, 2021

**Time**  
8AM & 4PM IST

**Duration**  
Live sessions of 45 minutes

**Interactive features**  
Join live polls  
Send in your questions

**Renowned experts in the field of clinical nutrition welcome you to listen and debate**

**Join the FREE webcast with 2 live sessions on:**  
Thursday May 27, 2021 - 8AM & 4PM IST

 <p><b>Prof. Leah Gramlich</b> Canada Introduction</p>	 <p><b>Dr. David Evans</b> United States Nutrition pathways for enhanced recovery after cancer surgery</p>
 <p><b>Dr. Isacco Montroni</b> Italy Malnutrition as a predictor for cancer surgery outcomes</p>	  <p><b>Prof. Stanislaw Klek</b> Poland <b>Dr. Rosario Caruso</b> Italy Prehabilitation and nutrition therapy; practical aspects for surgeons and nurses</p>

To learn more or to register for this event scan the QR CODE or visit:  
[www.nutritionevents.com](https://www.nutritionevents.com)

Fresenius Kabi Limited  
Fresenius Kabi Ireland  
Unit 3B Fingal Bay  
Ballybragan, Co. Dublin, Ireland  
Website: [www.fresenius-kabi.com/ie/](http://www.fresenius-kabi.com/ie/)  
Email: [FK-enquiries.ireland@fresenius-kabi.com](mailto:FK-enquiries.ireland@fresenius-kabi.com)  
Phone: +353 (0)1 841 3030

Job Code: FKJRL/Cen/003.21  
Date of Prep: April 2021

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

# 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.

This material is based on the work of the leading academic Dr Paul Stoltz, who has proved that GRIT is the quality most needed to survive the current global crisis.

We do hope you will be able to join us 'virtually'. Please contact your local representative for more information and to secure a place.

Fresenius Kabi understands and highly values the working relationships with all our hospital partners and we look forward to offering this series of meetings to the hardworking, dedicated HCPs in the HSE.

# Olive's message



It's extraordinary to think it's now over 12 months since life changed, but also wonderful to see how we have all adapted in our own ways and learned to meet new challenges that we have faced.

Thankfully, spring is finally here and the evenings are getting longer, and along with the hopes that lockdown restrictions will be soon eased, means there is light at the end of the tunnel for us all.

I look forward to seeing you soon, but as always, I am at the end of a phone if you need anything.

Take care.

**Olive**

---

Olive.Nolan@fresenius-kabi.com  
087-6183849

# 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<sub>2</sub>O 5.33 microgram, Copper chloride 2H<sub>2</sub>O 340 microgram, Ferric chloride 6H<sub>2</sub>O 540 microgram, Manganese chloride 4H<sub>2</sub>O 99 microgram, Potassium iodide 16.6 microgram, Sodium fluoride 210 microgram, Sodium molybdate 2H<sub>2</sub>O 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.

## 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

**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.

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](http://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.

## PRESCRIBING INFORMATION - SMOFKABIVEN® CENTRAL EMULSION FOR INFUSION.

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

**Active ingredients:** **1970ml bag** Amino acid solution with electrolytes 1000ml, Glucose 42% 595ml, Lipid emulsion 375ml - corresponding to: Soya-bean oil, refined 22.5g, Medium-chain triglycerides 22.5g, Olive oil, refined 18.8g, Fish oil, rich in omega-3-acids 11.3g, Glucose (monohydrate) 250g, Alanine 14.0g, Arginine 12.0g, Glycine 11.0g, Histidine 3.0g, Isoleucine 5.0g, Leucine 7.4g, Lysine (as acetate) 6.6g, Methionine 4.3g, Phenylalanine 5.1g, Proline 11.2g, Serine 6.5g, Taurine 1.0g, Threonine 4.4g, Tryptophan 2.0g, Tyrosine 0.40g, Valine 6.2g, Calcium chloride (as dihydrate) 0.56g, Sodium glycerophosphate (as hydrate) 4.2g, Magnesium sulphate (as heptahydrate) 1.2g, Potassium chloride 4.5g, Sodium acetate (as trihydrate) 3.4g, Zinc sulphate (as heptahydrate) 0.013g **1477ml bag** Amino acid solution with electrolytes 750ml, Glucose 42% 446ml, Lipid emulsion 281ml - corresponding to: Soya-bean oil, refined 16.9g, Medium-chain triglycerides 16.9g, Olive oil, refined 14.1g, Fish oil, rich in omega-3-acids 8.4g, Glucose (monohydrate) 187g, Alanine 10.5g, Arginine 9.0g, Glycine 8.2g, Histidine 2.2g, Isoleucine 3.8g, Leucine 5.6g, Lysine (as acetate) 5.0g, Methionine 3.2g, Phenylalanine 3.8g, Proline 8.4g, Serine 4.9g, Taurine 0.75g, Threonine 3.3g, Tryptophan 1.5g, Tyrosine 0.30g, Valine 4.6g, Calcium chloride (as dihydrate) 0.42g, Sodium glycerophosphate (as hydrate) 3.1g, Magnesium sulphate (as heptahydrate) 0.9g, Potassium chloride 3.4g, Sodium acetate (as trihydrate) 2.6g, Zinc sulphate (as heptahydrate) 0.0097g **986ml bag** Amino acid solution with electrolytes 500ml, Glucose 42% 298ml, Lipid emulsion 188ml - corresponding to: Soya-bean oil, refined 11.3g, Medium-chain triglycerides 11.3g, Olive oil, refined 9.4g, Fish oil, rich in omega-3-acids 5.6g, Glucose (monohydrate) 125g, Alanine 7.0g, Arginine 6.0g, Glycine 5.5g, Histidine 1.5g, Isoleucine 2.5g, Leucine 3.7g, Lysine (as acetate) 3.3g, Methionine 2.2g, Phenylalanine 2.6g, Proline 5.6g, Serine 3.2g, Taurine 0.50g, Threonine 2.2g, Tryptophan 1.0g, Tyrosine 0.20g, Valine 3.1g, Calcium chloride (as dihydrate) 0.28g, Sodium glycerophosphate (as hydrate) 2.1g, Magnesium sulphate (as heptahydrate) 0.60g, Potassium chloride 2.2g, Sodium acetate (as trihydrate) 1.7g, Zinc sulphate (as heptahydrate) 0.0065g **493ml bag** Amino acid solution with electrolytes 250ml, Glucose 42% 149ml, Lipid emulsion 94ml - corresponding to: Soya-bean oil, refined 5.6g, Medium-chain triglycerides 5.6g, Olive oil, refined 4.7g, Fish oil, rich in omega-3-acids 2.8g, Glucose (monohydrate) 63g, Alanine 3.5g, Arginine 3.0g, Glycine 2.8g, Histidine 0.8g, Isoleucine 1.3g, Leucine 1.9g, Lysine (as acetate) 1.7g, Methionine 1.1g, Phenylalanine 1.3g, Proline 2.8g, Serine 1.6g, Taurine 0.25g, Threonine 1.1g, Tryptophan 0.5g, Tyrosine 0.10g, Valine 1.6g, Calcium chloride (as dihydrate) 0.14g, Sodium glycerophosphate (as hydrate) 1.1g, Magnesium sulphate (as heptahydrate) 0.30g, Potassium chloride 1.1g, Sodium acetate (as trihydrate) 0.9g, Zinc sulphate (as heptahydrate) 0.0033g. **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 - The dose range of 13-31 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 35ml/kg bw/day. Infusion rate should not exceed 2.0ml/kg bw/hour (corresponding to 0.25g glucose, 0.10g amino acids, and 0.08g lipids /kg bw/hour). The recommended infusion period for adults is 14-24 hours.

Children (2-11 years) - The infusion rate should not exceed 2.4ml/kg bw/hour (corresponding to 0.30g glucose, 0.12g amino acids and 0.09g lipids /kg bw/hour). At the maximum infusion rate, do not use an infusion period of longer than 14 hours and 30 minutes. The recommended infusion period in children aged 2-11 is 12-24 hours. The recommended maximum daily dose is 35ml/kg bw/day. Adolescents - SmofKabiven Central 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 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, infants and children 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 4mmol/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. No clinical experience in children (aged 2 to 16/18 years). **Undesirable effects:** Common - Slight increase in body temperature. 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 08828/0187. IE - PA 2059/058/002 **Biofine Bags. 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:** 1970ml £67.73, 1477ml £64.05, 986ml £63.58, 493ml £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/SMOFKabiven-02.

## PRESCRIBING INFORMATION - SMOFKABIVEN® ELECTROLYTE FREE CENTRAL EMULSION FOR INFUSION.

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

**Active ingredients:** **1970ml bag** Amino acid solution 1000ml, Glucose 42% 595ml, Lipid emulsion 375ml - corresponding to: Soya-bean oil, refined 22.5g, Medium-chain triglycerides 22.5g, Olive oil, refined 18.8g, Fish oil, rich in omega-3-acids 11.3g, Glucose (monohydrate) 250g, Alanine 14.0g, Arginine 12.0g, Glycine 11.0g, Histidine 3.0g, Isoleucine 5.0g, Leucine 7.4g, Lysine (as acetate) 6.6g, Methionine 4.3g, Phenylalanine 5.1g, Proline 11.2g, Serine 6.5g, Taurine 1.0g, Threonine 4.4g, Tryptophan 2.0g, Tyrosine 0.40g, Valine 6.2g **1477ml bag** Amino acid solution 750ml, Glucose 42% 446ml, Lipid emulsion 281ml - corresponding to: Soya-bean oil, refined 16.9g, Medium-chain triglycerides 16.9g, Olive oil, refined 14.1g, Fish oil, rich in omega-3-acids 8.4g, Glucose (monohydrate) 187g, Alanine 10.5g, Arginine 9.0g, Glycine 8.2g, Histidine 2.2g, Isoleucine 3.8g, Leucine 5.6g, Lysine (as acetate) 5.0g, Methionine 3.2g, Phenylalanine 3.8g, Proline 8.4g, Serine 4.9g, Taurine 0.75g, Threonine 3.3g, Tryptophan 1.5g, Tyrosine 0.30g, Valine 4.6g **986ml bag** Amino acid solution 500ml, Glucose 42% 298ml, Lipid emulsion 188ml - corresponding to: Soya-bean oil, refined 11.3g, Medium-chain triglycerides 11.3g, Olive oil, refined 9.4g, Fish oil, rich in omega-3-acids 5.6g, Glucose (monohydrate) 125g, Alanine 7.0g, Arginine 6.0g, Glycine 5.5g, Histidine 1.5g, Isoleucine 2.5g, Leucine 3.7g, Lysine (as acetate) 3.3g, Methionine 2.2g, Phenylalanine 2.6g, Proline 5.6g, Serine 3.2g, Taurine 0.50g, Threonine 2.2g, Tryptophan 1.0g, Tyrosine 0.20g, Valine 3.1g **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 - The dose range of 13-31 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 35ml/kg bw/day. Infusion rate should not exceed 2.0ml/kg bw/hour (corresponding to 0.25g glucose, 0.10g amino acids, and 0.08g lipids /kg bw/hour). The recommended infusion period for adults is 14-24 hours. Children (2-11 years) - The infusion rate should not exceed 2.4ml/kg bw/hour (corresponding to 0.30g glucose, 0.12g amino acids and 0.09g lipids /kg bw/hour). At the maximum infusion rate, do not use an infusion period of longer than 14 hours and 30 minutes. The recommended infusion period in children aged 2-11 is 12-24 hours. The recommended maximum daily dose is 35ml/kg bw/day. Adolescents - Use as in adults. To provide total parenteral nutrition, trace elements, vitamins and 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 hemofiltration or dialysis, acute shock, uncontrolled hyperglycaemia, general contraindications to infusion therapy (acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency), hemophagocytotic syndrome, unstable conditions, infants and children 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 lactic acidosis, increased serum osmolality 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. 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 intake in patients with renal insufficiency. Monitor triglyceride levels (serum concentration should not exceed 4mmol/l during infusion), serum glucose, electrolytes, osmolality, fluid balance, acid-base status and liver enzyme tests. Electrolytes should be added governed by clinical condition of patient and by frequent monitoring of serum levels. 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. No clinical experience in children (aged 2 to 16/18 years). **Undesirable effects:** Common - Slight increase in body temperature. 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 08828/0188 IE - PPA 2059/059/002, PA 2059/059/001 **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:** 1970ml £67.73, 1477ml £64.05, 986ml £63.58 **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/SK-EFCentral-01.

## PRESCRIBING INFORMATION - SMOFKABIVEN® PERIPHERAL EMULSION FOR INFUSION.

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

**Active Ingredients: 1904ml bag** Amino acid solution with electrolytes 600ml, Glucose 13% 1036ml, Lipid emulsion 268ml - corresponding to: Soya-bean oil, (refined) 16.1g, Medium-chain triglycerides 16.1g, Olive oil, refined 13.4g, Fish oil, rich in omega-3 fatty acids 8.0g, Glucose (as monohydrate) 135g, Alanine 8.4g, Arginine 7.2g, Glycine 6.6g, Histidine 1.8g, Isoleucine 3.0g, Leucine 4.4g, Lysine (as acetate) 4.0g, Methionine 2.6g, Phenylalanine 3.1g, Proline 6.7g, Serine 3.9g, Taurine 0.6g, Threonine 2.6g, Tryptophan 1.2g, Tyrosine 0.24g, Valine 3.7g, Calcium chloride (as dihydrate) 0.34g, Sodium Glycerophosphate (as hydrate) 2.5g, Magnesium sulphate (as heptahydrate) 0.72g, Potassium chloride 2.7g, Sodium acetate (as trihydrate) 2.0g, Zinc sulphate (as heptahydrate) 0.008g **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 peripheral or central vein. The dose should be individualised to the patient's clinical condition, body weight (bw) and nutritional requirements. Adults - The dose range of 20 - 40ml/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 40ml/kg bw/day. The infusion rate should not exceed 3.0ml/kg body weight/hour (corresponding to 0.21g glucose, 0.10g amino acids, and 0.08g lipids/kg bw/hour). The recommended infusion period is 14 - 24 hours. Children (2-11 years) - The infusion rate should not exceed 3.0ml/kg bw/hour (corresponding to 0.10g amino acids, 0.21g glucose and 0.08g lipids/kg bw/hour). The recommended infusion period is 12 - 24 hours. Recommended maximum daily dose is 40ml/kg bw/day. If using maximum daily dose, dose should be infused during a period of at least 13 hours. Adolescents - SmofKabiven Peripheral can be used as in adults. To provide total parenteral nutrition, trace elements, vitamins and possibly electrolytes should be added to SmofKabiven Peripheral 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, infants and children under 2 years of age. **Special warnings and precautions for use (see SmPC for full details):** 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 4mmol/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. No clinical experience in children (aged 2 to 16/18 years). Thrombophlebitis may occur if peripheral veins are used for infusions. **Undesirable effects:** Common - Thrombophlebitis, slight increase in body temperature. 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 08828/0213, IE - PA 2059/061/002 **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:** 1904ml bag £63.84. **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/SK-Peripheral-01.

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

Fresenius Kabi Limited. Fresenius Kabi Ireland. Unit 3B Fingal Bay Business Park, Balbriggan, Co. Dublin, Ireland. Phone: +353 (0)1 841 3030 Email: FK-enquiries.Ireland@fresenius-kabi.com

© Fresenius Kabi Ireland. Job code: PN/Gen.024.21 | Date of preparation: May 2021

 **FRESENIUS  
KABI**  
caring for life