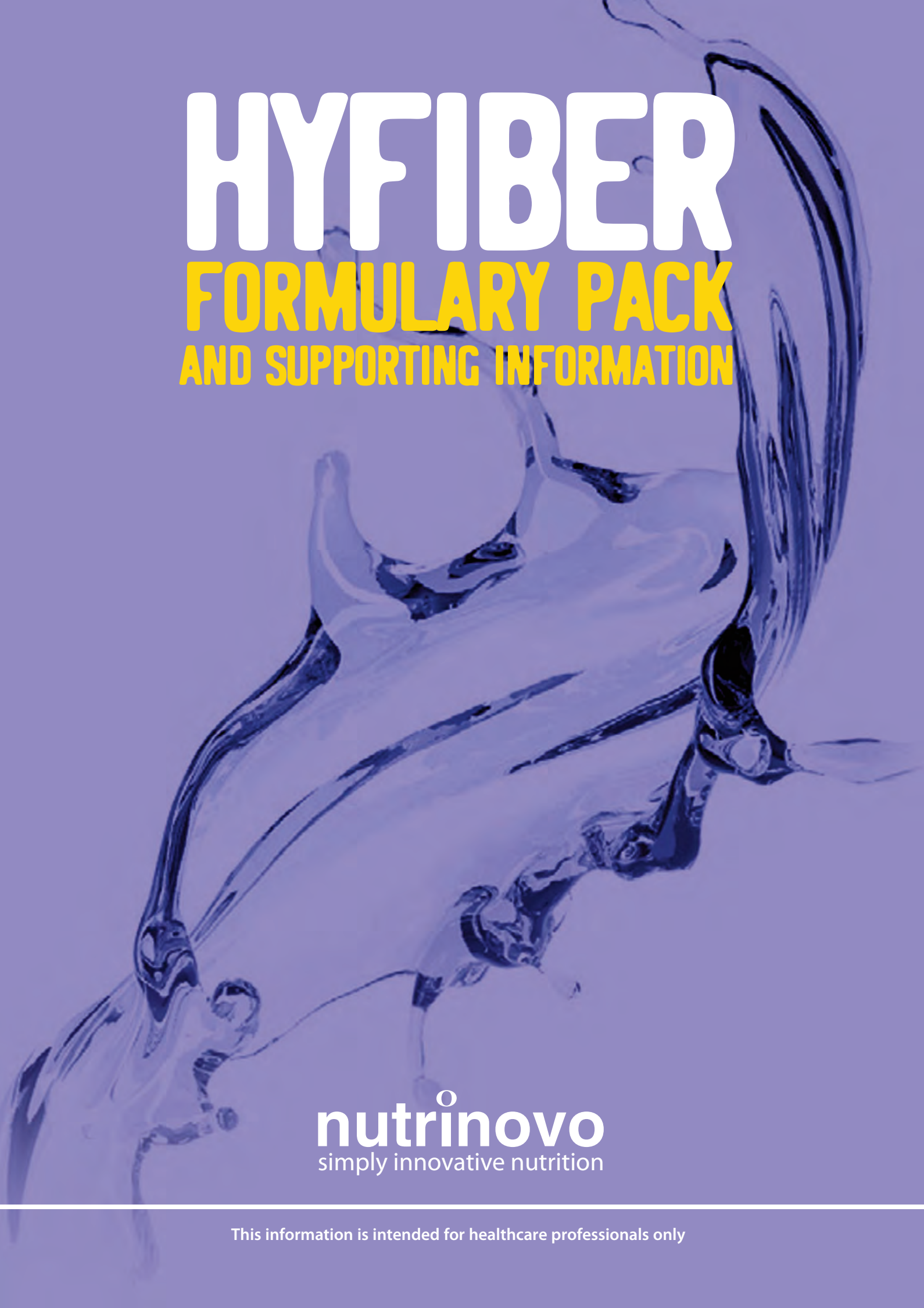

HYFIBER

FORMULARY PACK

AND SUPPORTING INFORMATION

nutrinovo

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This information is intended for healthcare professionals only

Dietetic Summary

The beneficial effects of dietary fibre on gut health are widely recognised; however, fibre intakes in the UK are often inadequate with few people achieving recommended targets. Inadequate fibre intake can contribute to bowel transit disorders such as constipation; a condition which affects many people in the UK and contributes significant costs to the NHS.

For some patients there are barriers to achieving an adequate fibre intake, either through normal diet or enteral tube feeding, and fibre supplements may be required. Fibre supplements can support patients to increase their fibre intake, which can in turn lead to beneficial changes in bowel transit.

HyFIBER is a low volume, liquid fibre supplement containing 12g of soluble fibre in each 30ml serving. It can be taken orally or administered via an enteral feeding tube, allowing health care professionals to tailor fibre supplementation to the specific needs of individual patients.

HyFIBER is a Food for Special Medical Purposes, for use under medical supervision and is ACBS approved for the dietary management of bowel transit disorders.

This document provides supporting information for the use of HyFIBER and can be used to aid the completion of formulary applications.

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Contents

Key Product Features

Liquid fibre supplement

Concentrated source of soluble fibre – 12g in 30ml serving

Ready to use – no premixing required

Low volume

Low in electrolytes

Fat free

IDDSI level 0

Mild citrus flavour

Available in single serve 30ml sachets and multi-serve 887ml bottles

Fibre Source

HyFIBER contains:

- 10.3g Polydextrose
- 1.7g Fructooligosaccharides (FOS).

Nutritional Composition

Composition	Unit	Amount per serving (30ml)	Amount per 100ml
Energy	Kcal KJ	36 145	119 484
Fat	g	0	0
Carbohydrates ***of which sugars***	g g	3.1 3.1	10.4 10.4
Fibre	g	12	39
Protein	g	0	0
Minerals			
Sodium	mg (mmol)	2.77 (0.12)	9.22 (0.4)
Potassium	mg (mmol)	6.13 (0.16)	20.44 (0.52)
Phosphorous	mg (mmol)	0	0
Calcium	mg (mmol)	0	0

Osmolality level of 330 mOsm/kg

No added micronutrients.

Indication

HyFIBER is ACBS approved for the dietary management of bowel transit disorders.

Suitability

Allergen free - free from the 14 main food allergens

Suitable for vegetarian and vegan diets

Halal and kosher diets – HyFIBER contains no ingredients that would be restricted on these diets; however HyFIBER is not halal or kosher certified.

Precautions and Contra-indications

Must be used under strict medical supervision

For enteral or oral use only

Not suitable as a sole source of nutrition

Not recommended for children under 3 years of age.

Product Codes and Prices

Single unit size	Ordering unit	List price	PIP code	Case barcode	Product code	Cost per 30ml serving	Cost per gram fibre
30ml sachet	100 x 30ml sachet	£103.90/€119.99	405-2882	0794688184946	18494	£1.04	£0.087
887ml Bottle	2 x 887ml bottle	£60.80/€70	417-3209	0794688184960	18496	£1.03	£0.086

The list price of the products is available from the following sources:

- Drug Tariff
- BNF/BNFc
- MIMs
- Nutrinovo website (under codes and prices).

Please contact your Regional Account Manager to discuss pricing options.

Shelf Life and Storage

HyFIBER has a shelf life of 24 months from date of manufacture

Store at room temperature (not exceeding 25°C)

Sachets: Once opened, use immediately

Bottles: Once opened, use within 3 months.

Dosage

The dosage of HyFIBER should be determined by a clinician or dietitian and is dependent on the age and medical condition of the patient

- It is recommended that the addition of HyFIBER should be gradually increased to meet individual requirements
- As a guide:
  - Start with 30ml per day for the first week
  - Increase to 60ml per day in split doses if required
- Bowel medication may need to be adjusted as the dose of HyFIBER is increased.

Administration Guidance

HyFIBER is suitable for oral and enteral administration

- For oral consumption, HyFIBER can be taken neat or mixed into hot or cold, foods and drinks
- For enteral use, administer HyFIBER via enteral feeding tube using a suitable enteral syringe. The tube should be flushed before and after administration of HyFIBER.

Product Evaluation

An open labelled study into the gastrointestinal tolerance and compliance of HyFIBER (1-2 sachets per day) showed it to be well tolerated, with high patient compliance (93%) when administered via an enteral feeding tube (n=23). Nursing staff also found the product very easy to administer via a feeding tube*.

Further data was collected from an audit of renal patients (n=15) who were taking HyFIBER orally (1-3 sachets per day). In this audit, HyFIBER scored highly for compliance (97%), ease of use (93%) and overall acceptability (93%). 80% of participants found HyFIBER pleasant to take**.

*Nutrinovo ACBS application for HyFIBER 2019, data on file. **Nutrinovo ACBS application for HyFIBER 2022, data on file.

It is well established that dietary fibre is an essential component of a healthy diet. A diet higher in dietary fibre is associated with a lower incidence of a variety of conditions such as cardiovascular disease, coronary events, type 2 diabetes mellitus and colorectal cancer. Dietary fibre also has a beneficial effect on constipation, decreasing intestinal transit times and increasing faecal mass.[1]

According to the Scientific Advisory Committee on Nutrition (SACN) report on Carbohydrates in Health, published in 2015, the dietary reference value (DRV) for the average population intake of dietary fibre for adults is 30g/day.[1]

Statistics show that fibre intake is inadequate for most of the UK adult population with only 9% of 19-74 year olds, and 3% of those aged 75 years and over meeting the DRV. Mean daily fibre intake of 19–74-year-olds and those 75 years and over, is 19.7g and 17.3g respectively. These figures indicate deficits in fibre intake of between 10.3 and 12.7g per day. Inadequacies in fibre intake are also seen in children.[2]

Fibre and Nutrition Support

In addition to the importance of fibre in the general population, the provision of adequate fibre should be an important consideration in patients requiring nutrition support. The National Institute for Health and Care Excellence (NICE) guidelines on nutrition support for adults highlight that 'total nutrient intake of people prescribed nutrition support accounts for energy, protein, fluid, electrolyte, mineral, micronutrients and fibre needs'.[3] This applies to both patients receiving oral nutrition support and enteral tube feeding.

A systematic review and meta-analysis evaluating the clinical and physiological effects of fibre-containing enteral formulae (51 studies; 43 RCT; 1591 patients, 171 healthy volunteers), found that fibre supplementation was generally well tolerated and had a moderating effect on bowel function. Fibre was shown to reduce bowel frequency when baseline frequency was high and increase it when it was low, suggesting beneficial effects on both constipation and diarrhoea. The authors concluded that 'first-line treatment with fibre-containing feeds should be considered an important modality of clinical care'.[4]

The benefit of fibre in enteral nutrition is recognised in several recent European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines. The ESPEN practical guideline for clinical nutrition and hydration in geriatrics recommend that for enteral nutrition, fibre containing products should be used. This is out of recognition that older patients often suffer from gastrointestinal problems including constipation and diarrhoea, and that dietary fibre can help to normalise bowel function. The guidelines states that 'there is no reason to omit dietary fibre if bowel function is not compromised' and 'enterally nourished patients should not be deprived of the well-known beneficial metabolic effects of dietary fiber'.[5] Similarly, The ESPEN practical guideline for home enteral nutrition recommends that fibre containing feeds shall normally be used for patients with diarrhoea, and for patients with constipation.[6]

Barriers to Adequate Fibre Intake

For some patient groups, modification of the diet to increase fibre intake is not practical or not possible due to a variety of factors. In renal patients, dietary restriction of potassium or phosphate can limit intake of dietary fibre from fibre rich food sources such as fruit, vegetables, pulses, and wholegrains. Patients with reduced oral intake or a small appetite may also struggle to consume adequate fibre due to volume of food that this may add to their diet.

The low volume and low electrolyte content of HyFIBER makes it a suitable option to supplement the fibre intake of individuals who are unable to meet their fibre requirements due to dietary restrictions, fluid restrictions or poor appetite.

There can also be challenges associated with achieving adequate fibre intake for patients requiring oral nutritional supplements (ONS) or enteral tube feeding.

There are significantly more fibre free than fibre containing adult ONS available,[7] and for particular types of ONS, such as savoury, juice, dessert or yoghurt style, or high protein ONS, fibre options are either not available or very limited. Fibre containing ONS typically provide between 2 - 5g of fibre per serving.[8] For patients unable to consume sufficient fibre from other sources due to dietary restrictions or poor food intake, even supplementation with 2-3 servings of fibre containing ONS (total fibre content 6g - 15g) is likely to fall short of the recommended intake of 30g per day.[1]

Not all patients receiving ONS will require fibre supplementation, however for those that do, HyFIBER can be used to provide additional fibre alongside either fibre containing or fibre free ONS.

In a survey of 179 UK dietitians, a number of challenges to adequate fibre provision in home enteral tube feeding patients were identified. These included issues with patient tolerance to fibre containing feeds, and standard fibre containing feeds not meeting tube-fed patients' fibre requirements, with fibre contents either too low or too high.[9] Instances where the fibre content of an enteral feed is too low can occur in patients with low energy requirements, meaning the volume of feed required does not meet fibre requirements. In other instances, patients may require specialist feeds that do not come in a fibre containing version.

Standard adult enteral tube feed products typically contain a mix of fibre sources in a fixed quantity. Although a combination of feeds can be used to alter the mix of fibre sources and dose of fibre for individual patients, this may represent additional burden and/or cost for the patient, their carer, dietetic services and commercial feed companies due to frequent or complex changes in feed regimens.

HyFIBER offers a flexible solution for the provision of dietary fibre during enteral tube feeding that can be titrated to meet individual patient needs.

Fibre containing ready to drink ONS and fibre containing enteral tube feeds are often more expensive than their non-fibre containing equivalents.[10] Using HyFIBER alongside a non-fibre ONS or tube feed can provide a cost saving option for meeting patients' fibre requirements (**Table 1** and **2**).[8, 10]

Table 1. Cost comparison of non-fibre feed, fibre containing feed, and non-fibre feed plus HyFIBER.

Cost of non-fibre feed	Cost of fibre feed	Fibre content of fibre feed	Cost of non-fibre feed plus HyFIBER*	Cost saving per day**
Nutrison Energy 1500ml pack	Nutrison Energy Multifibre 1500ml pack			
£21.71	£24.85	22.5g	£23.64	**£1.21**
Osmolite 1.5kcal 1500ml pack	Jevity 1.5kcal 1500ml pack			
£22.29	£25.54	33g	£25.12	**£0.42**
Fresubin HP Energy 1000ml pack	Fresubin HP Energy Fibre 1000ml pack			
£13.74	£15.14	15g	£15.03	**£0.11**

*Equivalent amount of fibre to the fibre containing feed **Cost saving of using non-fibre feed with HyFIBER, compared to fibre feed. Dependent on individual patient requirements.

Table 2. Cost comparison of non-fibre ONS, fibre containing ONS, and non-fibre ONS plus HyFIBER.

Cost of non-fibre ONS	Cost of fibre ONS	Fibre content of fibre feed	Cost of non-fibre feed plus HyFIBER*	Cost saving per day**
2 x 125ml Fortisip Compact	2 x 125ml Fortisip Compact Fibre			
£2.96	£4.40	9g	£3.73	**£0.67**
2 x 200ml Ensure Plus	2 x 200ml Ensure Plus Fibre			
£2.66	£5.34	10g	£3.52	**£1.82**
2 x 200ml Fresubin Energy	2 x 200ml Fresubin Energy Fibre			
£2.98	£5.12	8g	£3.67	**£1.45**

*Equivalent amount of fibre to the fibre containing ONS **Cost saving of using non-fibre ONS with HyFIBER, compared to fibre containing ONS. Dependent on individual patient requirements.

Constipation is a common bowel transit disorder, estimated to affect around 1 in 7 adults and up to 1 in 3 children in the UK, at any one time.[11] Chronic constipation has been found to affect up to 14% of the population, equivalent to 9 million people in the UK.[12] Constipation is particularly common in the elderly, affecting a third of people over the age of 60,[13] and over 50% of nursing home residents.[14]

Constipation contributes significant costs to the NHS and negatively impacts on patients quality of life.[15] The cost of constipation extends beyond the use of laxatives, with elective and non-elective hospital admissions, GP appointments, home visits and other healthcare costs all contributing to the overall costs associated with its management.[15]

Laxatives are commonly used in the management of constipation, and although they are required in some cases, they are typically only recommended if diet and lifestyle changes haven't helped.[16] Inadequate dietary fibre intake can contribute to constipation[17] and increasing dietary fibre is one aspect of the diet and lifestyle changes which are recommended as first line management of constipation.[18, 19]

Several large cohort studies have shown positive associations between higher intakes of dietary fibre and both stool frequency[20] and prevalence of constipation.[21, 22] A number of systematic reviews have also demonstrated that fibre supplementation has beneficial effects on stool frequency and consistency.[23, 24, 25]

In addition to its beneficial role in managing constipation, soluble fibre can also be beneficial in the management of diarrhoea. The water holding capacity of non-fermentable soluble fibres, whilst softening hard stools can also help to firm up loose stools.[26] Additionally, short chain fatty acids (SCFAs) produced from the fermentation of fibre can stimulate water and sodium absorption in the colon, which may have a beneficial effect on diarrhoea.[4, 27]

HyFIBER may therefore be beneficial in the dietary management of individuals with constipation, diarrhoea, or fluctuating bowel habits. The use of HyFIBER can also be a useful way of demonstrating the beneficial effects of increased dietary fibre on bowel transit. This may in turn motivate individuals to make dietary changes to increase their fibre intake through their normal diet.

The soluble fibre sources in HyFIBER are polydextrose and FOS.

Polydextrose

Polydextrose is a water-soluble polymer of glucose that is widely used across most sectors of the food industry and has a reported energy value of one calorie per gram.[28, 29] Studies looking at the use of polydextrose in bowel health have shown that it increases faecal bulk, increases stool frequency, and improves stool consistency.[30, 31, 32, 33] It is also recognised that polydextrose may have prebiotic potential.[28]

Polydextrose resists hydrolysis by digestive enzymes in the small intestine and reaches the colon intact.[34] In the colon polydextrose is slowly and partially fermented by gut bacteria, with up to 60% excreted in the faeces.[28]

Polydextrose contributes to bowel function through the formation of bacterial cell mass from its fermentable portion, and the water holding capacity of the fraction that is not fermented, both of which contribute to an increase in stool bulk.[34]

Polydextrose has been widely demonstrated to be well tolerated in human intervention studies, likely owing to its gradual fermentation in the gut.[28] In addition, the risk of excessive bowel movements from polydextrose is small. A recent European Food Safety Authority report evaluating polydextrose as a food additive agreed with previous reports that the laxative threshold for polydextrose is 90 g/day or 50 g as a single dose.[35] This suggests a wide margin between the amounts demonstrated to be beneficial and the amounts which may result in a negative effect.

FOS

FOS are indigestible short chain fructan compounds which are found in a wide range of foods and are widely recognised for their prebiotic potential.[36] Studies looking at the effect of fructans on bowel function have found that they can increase stool frequency and improve stool consistency.[37, 38, 39]

In contrast to polydextrose which is slowly and partially fermented, FOS is rapidly and completely fermented by the microbiota in the colon.[40, 41] This stimulates the growth of beneficial bacteria, results in the production of SCFAs and a decrease in luminal pH, as well as an increase in microbial mass.[42] SCFAs can influence the physiology of the colon and promote colonic motility.[43, 44] Despite their rapid fermentation, studies show that daily doses of up to 10-12g of fructans do not generally result in significant gastrointestinal symptoms.[37]

Supporting Studies

A number of research studies have been published evaluating the effects of polydextrose and FOS on bowel health.

Polydextrose

A placebo-controlled, double blind, randomized trial investigated the effects of 0, 4, 8 and 12g polydextrose, taken daily for 4 weeks, in 120 healthy adults and found multiple improvements in bowel health. Frequency and ease of defecation improved significantly in all groups of polydextrose, in a dose dependent manner and faecal weight increased significantly after 12g polydextrose. Beneficial changes were also seen in SCFA production, faecal pH and faecal microflora. There were no reports of abdominal distention, abdominal cramps or diarrhoea in participants taking polydextrose.[30]

A 3-arm, crossover study in 36 healthy adults compared the effects of 20g polydextrose, 20g soluble corn fibre and a low fibre control, each taken daily for 10 days. Compared to the control group, polydextrose supplementation resulted in a significant increase in stool weight and stool frequency, and stools were also significantly softer.[31]

Several studies have investigated the effects of polydextrose in constipated individuals. A parallel design, placebo-controlled trial evaluated the effects of 10g polydextrose, taken daily for 4 weeks, in 29 constipated haemodialysis patients. Those in the polydextrose group had a significant increase in stool frequency from 3.0 to 8.5 times per week. The increase in stool frequency was also significantly increased compared to the control group, and remained significantly increased after the ingestion period. Ratings of abdominal distention showed no significant differences between the groups and there were no reports of abdominal cramps, diarrhoea or other discomforts.[32]

A 4-arm study compared the effects of 0, 4, 8 or 12g polydextrose per day, for 2 weeks, in 192 functionally constipated patients. Those who consumed 12g polydextrose per day saw a significant increase in stool frequency by more than 2 bowel movements per week, compared to placebo. Additionally, degree of straining was significantly decreased, and proportion of complete bowel movements significantly increased, after both 8 and 12g PDX.[33]

FOS

A systematic review of 47 studies found that stool frequency, stool consistency and stool wet weights were significantly increased after supplementation with short chain β-fructans.[37]

A cross-over study in 9 elderly, constipated peritoneal dialysis patients, showed that 20g FOS supplementation per day for 30 days resulted in significant improvements in stool frequency, colonic transit time and stool consistency from type 1 to type 4 stools. Although some initial gastrointestinal symptoms (mild flatulence and abdominal discomfort) were experienced by 3 patients, a dose reduction to 10g per day for the first 2-3 days alleviated these, allowing successful dose increase back to 20g per day.[38]

In a randomised, double blind, parallel design trial, the effect of FOS supplementation compared to a placebo was evaluated in 97 healthy adult participants with ≤3 bowel movements per week and habitual low dietary fibre intake. FOS was initially supplemented at 5g per day, then increased to 10g and then 15g for 4-week periods at a time. Stool frequency increased as the dose of FOS increased, with a significant increase seen at 15g per day. There were no adverse effects on gastrointestinal symptoms in the FOS group, and values for noise, pressure and pain significantly decreased for participants taking higher doses of FOS.[45]

Polydextrose and FOS

A recent prospective, non-comparative, interventional study evaluated the effect of a product containing both polydextrose and FOS, on constipation in children. The product, which contained 4.17g polydextrose and 0.45g FOS, was taken daily for 45 days by 77 children (4-8 years). During the intervention there was a significant progressive increase in the weekly frequency of bowel movements, and a significant reduction in children with fewer than three bowel movements per week, defecation of Bristol type 1 and 2 stools, pain on defecation, fear of defecation, and abdominal pain. A significant reduction in faecal pH was also seen.[46]

Based on the published literature, the sources of soluble fibre in HyFIBER, polydextrose and FOS, help to normalise bowel function and can play a role in the dietary management of constipation.

In summary, HyFIBER can be beneficial in the following situations to support patients to increase their fibre intakes and support the dietary management of bowel transit disorders:

- To supplement fibre intake for patients requiring ONS, where fibre containing ONS are unavailable or provide inadequate fibre, or as a cost saving to fibre containing ONS
- To supplement fibre intake alongside other methods of oral nutrition support such as dietary modification, food fortification and homemade high protein and energy drinks
- To supplement fibre intake for patients who are unable to meet fibre requirements due to dietary restrictions e.g., renal patients
- To supplement fibre intake for patients who require texture modified foods which may restrict fibre intake
- To supplement fibre intake for patients requiring enteral tube feeding, where fibre containing feeds are not available, or contain inappropriate amounts or types of fibre, or as a cost saving to fibre containing feeds
- To support the management of bowel transit disorders such as diarrhoea and constipation
- To demonstrate the beneficial effects of increased dietary fibre and motivate patients to increase their fibre intake through their diet.

Product Support Services

Nutrinovo produce a comprehensive range of supporting materials designed specifically and independently to support both health care professionals & patients.

Further information including the following materials can be found at:
www.nutrinovo.com/resource-centre/ or scan the QR Code.

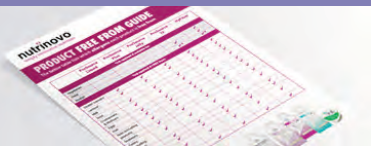
Case Studies & Articles

Data Sheets

Patient Information Leaflets

Product Brochures

Product Allergen Information

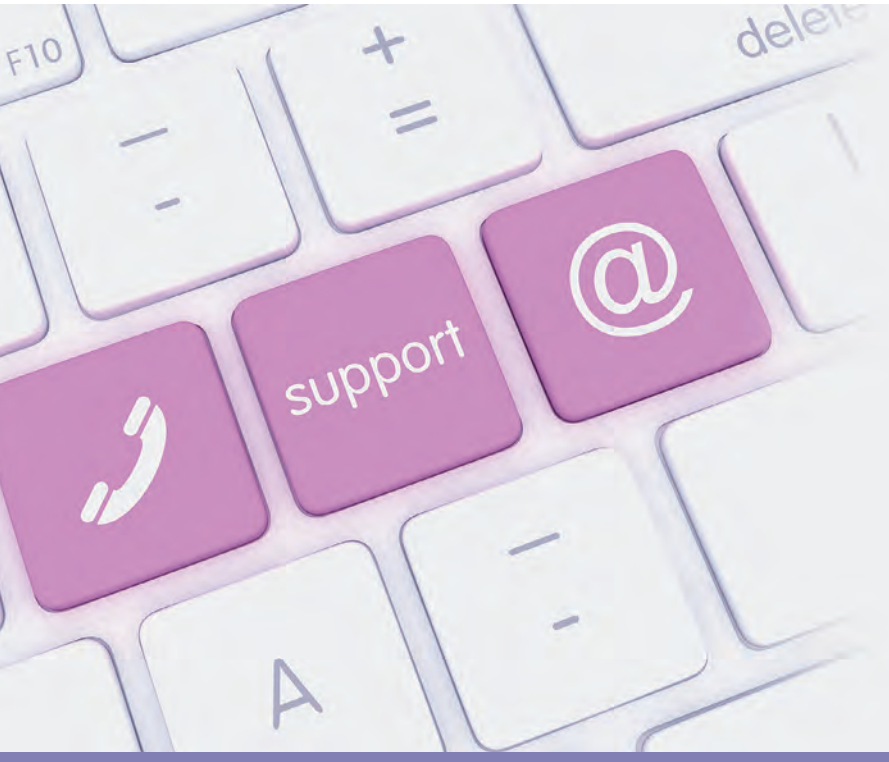


Product IDDSI Levels

Product Usage Guidelines

Video Library

Podcasts and Webinars



Other support services include:

- Free sample service
- User helpline: +44 (0)1249 691301
- Easy contact form
- Request a visit form
- Product feedback submission form.

For any further information please contact us:

Telephone: 44 (0)1249 691301
Email: info@nutrinovo.com

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