

## FORMULARY GUIDE: **FORTISIP COMPACT PROTEIN FOR MALNUTRITION IN COPD**

The British Lung Foundation (BLF) estimates that 1.2 million people in the UK have diagnosed chronic obstructive pulmonary disease (COPD). Indeed, about 2% of the UK population – 4.5% of people over 40 years of age – live with diagnosed COPD. However, up to two-thirds of people with COPD may remain undiagnosed.<sup>1</sup>

COPD commonly causes morbidity and mortality. COPD, for example, accounts for 5.3% of deaths<sup>1</sup> and is the second most common cause of emergency hospital admissions in the UK. Many of these admissions are preventable.<sup>2</sup>

The 2017 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines comment that weight loss and anorexia are common in severe and very severe COPD and can influence prognosis.<sup>3</sup> For example, resting energy expenditure is 15-20% above predicted in people with COPD, probably reflecting the increased energy required for breathing.<sup>4</sup> COPD is also often associated with elevated protein turnover and increased antioxidant requirements.<sup>5, 6</sup> However, patients do not seem to adjust their diet to compensate.<sup>6, 7</sup>

This information is intended for healthcare professionals only.

Fortisip Compact Protein is a Food for Special Medical Purposes for the dietary management of disease related malnutrition and must be used under medical supervision.

## Consequences of malnutrition in COPD

Because of the increased metabolic demand, malnutrition is common in patients with COPD. Using the Malnutrition Universal Screening Tool (MUST), a study from the UK estimated that approximately 21% of outpatients with COPD were at medium (7%) or high risk (14%) of malnutrition. Another UK study reported that about 35% of in-patients with an acute exacerbation of COPD were at medium (10.4%) or high risk (24.8%) of malnutrition.<sup>9</sup>

The aforementioned UK study outlines that patients with COPD who have a MUST score of  $\geq 2$  had a significantly increased risk of in hospital death (odds ratio 2.10) and early readmission (odds ratio 1.71). Additionally, patients who had lost more than 10% weight were almost 4 times more likely to have an early readmission (Table 1).<sup>9</sup>

In patients with COPD, disease-related malnutrition is associated with impaired pulmonary status - such as a decrease in strength and endurance of the respiratory muscles, increased gas trapping and a lower exercise capacity.<sup>4, 10, 11</sup> Malnutrition in COPD is also associated with decreased health-related quality of life (HRQoL)<sup>10</sup> and can increase the frequency of, and impair recovery from, respiratory and other infections. In turn, infections can increase the metabolic rate.<sup>4, 12</sup>

Exacerbations drive much of the morbidity and mortality associated

Outcome		% of patients enrolled	Odds ratio for in-hospital mortality	Odds ratio for early readmission
BMI (kg/m <sup>2</sup> )	<18.5	17.8	2.50*	0.86
	18.5-24.9	37.5	1 (comparator)	1 (comparator)
	25-29.9	25.0	1.03	0.54*
	>30	19.7	0.89	0.80
Weight loss (%)	<5	79.3	1 (comparator)	1 (comparator)
	5-10	11.2	1.52	1.36
	>10	9.5	1.59	3.90*
MUST score	0	64.8	1 (comparator)	1 (comparator)
	1	10.4	1.46	1.24
	$\geq 2$	24.8	2.10*	1.71*

\* p<0.05 An odds ratio of 2 indicates a doubling in risk; odds ratio of 1.71 indicates a 71% increase

Table 1: Malnutrition (high-risk MUST score) predicts in-patient death and early readmission<sup>9</sup>

Outcome		Malnourished (n=47)	Nourished (n=239)
Mortality at:	1 year (%)	27.7*	12.1
	2 years (%)	40.4*	18.0
Mean length of stay (days)	Emergency admissions	11.57*	6.67

Table 2: Mortality and healthcare resource use in malnourished and nourished COPD patients admitted to hospital<sup>14</sup>

with COPD. About 8-12% of people admitted with COPD died in hospital, for example, while 23-28% died within 1 year.<sup>13, 14</sup> Low body mass index (BMI) at baseline and weight loss during follow-up are independent risk factors for a COPD exacerbation.<sup>15</sup> Body weight, BMI and muscle mass independently predict mortality and length of stay in patients with COPD.<sup>4, 9, 12, 14</sup> A pilot study from Australia reported that malnourished in-patients with COPD were almost three times (odds ratio: 2.93) more likely to die within a year of initial presentation than those who were well nourished. Malnourished in-patients also had almost twice the length of stay (table 2).<sup>14</sup>

Against this background, several systematic reviews and meta-analyses show that nutritional supplementation reverses some of the adverse functional consequences of severe COPD,<sup>11</sup> promotes significant weight gain (especially in malnourished people), and improves body composition, exercise tolerance, respiratory muscle strength, handgrip strength and HRQoL.<sup>10, 11</sup>

## Guideline recommendations

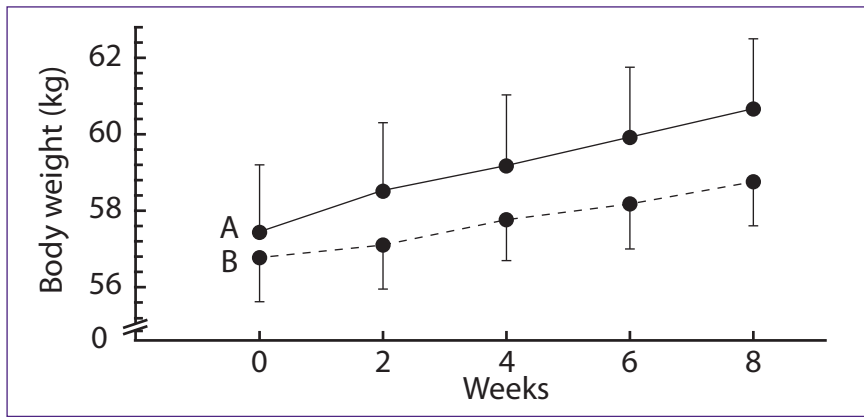
NICE recommends screening all patients for malnutrition risk using a validated screening tool, such as MUST (available from [www.bapen.org.uk](http://www.bapen.org.uk)),<sup>16</sup> and calculating BMI in patients with COPD.<sup>17</sup> Healthcare professionals (HCPs) should refer patients with high, low or variable BMI for dietetic advice. Patients with low BMI should also receive nutritional supplements to increase their total calorific intake. HCPs should encourage people to exercise to augment the effects of nutritional supplementation.<sup>17</sup>

In addition to low BMI, COPD appears to be associated with elevated body protein synthesis and breakdown compared to healthy controls, which may reflect the enhanced acute phase protein synthesis that is associated with low-grade inflammation.<sup>5</sup> Numerous inflammatory markers are elevated in patients with COPD<sup>10</sup> and muscle wasting can even occur in patients with normal stable weight.<sup>5</sup>

Against this background, a systematic review involving 36 randomised controlled trials encompassing 3790 patients with COPD or a variety of other diseases reported that high-protein nutritional supplements (>20% energy from protein) were associated with a 19% reduced risk of complications and 30% fewer hospital readmissions.<sup>12</sup> Handgrip strength, which predicts outcomes in COPD,<sup>11</sup> improved by 1.76kg.<sup>12</sup> Supplementation does not seem to reduce voluntary food intake.<sup>12</sup>

Length of prescription	Bottles per day	Volume
1 month (28 days)	1	3500ml
	2	7000ml
2 months (56 days)	1	7000ml
	2	14000ml
3 months (84 days)	1	10500ml
	2	21000ml

Table 3: Bottles per month in ml for prescription request



**Figure 1: Course of body weight per 2 weeks during 8 weeks of nutritional therapy.<sup>7</sup> The change in body weight of group A taking low-volume, high-energy supplement (—) was significantly higher than that of group B taking standard size supplement (---) kg; P=0.014).**

Optimising intake of protein and essential amino acids may stimulate protein synthesis, enhance the efficacy of anabolic drugs and physiological stimuli, such as resistance exercise<sup>5</sup> and pulmonary rehabilitation.<sup>7</sup> However, the volume of the supplement may be important.

Patients with stable COPD who received low-volume (125ml), high-energy, high-protein nutritional supplements after 8 weeks of pulmonary rehabilitation gained more weight (mean 3.3kg) than those taking a standard size (200ml) supplement of similar macronutrient composition (2.0 kg see figure 1).<sup>7</sup>

### Economic benefits

COPD and malnutrition exert heavy economic tolls. The pilot study from Australia reported that malnourished in-patients had almost twice the length of stay at almost double the cost as their nourished counterparts.<sup>14</sup>

The BLF estimate that COPD costs the UK economy £48.5 billion a year. Direct costs account for £1.8 billion, indirect costs (e.g. lost productivity) for £61.0 million and intangible costs (e.g. pain, suffering and excess mortality) for £46.6 billion.<sup>18</sup> Malnutrition accounts for about 15% of total expenditure on health and social care in England. More than 90% of malnourished people are in the community.<sup>19</sup>

Against this background, nutritional supplements yield a return that is between 2 and 5 times, depending on the economic model, greater than the investment.<sup>19</sup> In a study of patients hospitalised with COPD, nutritional supplements reduced length of stay (by 22%), readmission rates (24.8% vs

26.6%) and hospital costs compared to usual care.<sup>20</sup>

### Fortisip Compact Protein

Fortisip Compact Protein is a high-energy (2.4kcal/ml), high-protein (18g protein/125ml bottle), ready-to-drink, milkshake-style nutritional supplement for the dietary management of disease-related malnutrition, including that associated with COPD. It is a food for special medical purposes for use under medical supervision. The recommended dose is 1 or 2 bottles per day, unless specified otherwise by a clinician or dietitian. The total volume required for prescription requests of a duration of 1 to 3 months are outlined in (Table 3).

Fortisip Compact Protein can supplement the diets of patients with COPD who are unable to meet their nutritional requirements from other foods. One bottle of Fortisip Compact Protein provides at least 25% of the Reference Nutrient Intake (RNI) of vitamins, minerals and trace elements. There are a range of flavours available, outlined in Table 4. Consider a Fortisip Compact Starter Pack to ascertain the patient's flavour preference. The pack contains 6 x 125ml bottles, one of each flavour.

Flavour	Unit size	Shelf life
Vanilla Strawberry Banana Mocha Peach-mango Berries	125ml bottle	12 months

**Table 4: Fortisip is available in a range of flavours to account for patient preference**

Energy	Per 125ml	300kcal
Fat	Per 125ml	11.8g
	% of total energy	35.3
	As saturates	1.1g
Carbohydrate	Per 125ml	30.5g
	% of total energy	40.7
	As sugars	16.6g
Protein	Per 125ml	18g
	% of total energy	24
Vitamin and minerals	Per 125ml	25% of RNI

**Table 5: Average nutritional content of Fortisip Compact Protein per 125ml bottle**

Moreover, patients with COPD show increased oxidative stress (e.g. leading to free radical damage), which reduces airflow. So, patients with COPD need increased levels of antioxidant nutrients.<sup>6</sup> A study from Spain, however, reported that the diets of patients with COPD included lower levels of antioxidants, especially vitamins C and E, than healthy controls.<sup>6</sup>

### Conclusion

COPD is common and associated with considerable morbidity, mortality and expense.<sup>1,18</sup> Malnutrition is frequent in patients with COPD<sup>5,11</sup> and is associated with worse outcomes including increased mortality.<sup>4,10,11</sup> COPD is often associated with elevated protein turnover, muscle wasting and resting energy expenditure, even in people of normal stable weight, as well as deficiencies in certain micronutrients.<sup>4-6,21</sup>

Increasing evidence suggests that nutritional supplements, recommended by NICE for some patients, improve clinical and economic outcomes in COPD.<sup>17,20</sup>

## Summary

- In the UK, approximately 21% of outpatients with COPD and about 35% of in-patients with an acute exacerbation of COPD were at risk of malnutrition.<sup>8,9</sup>
- In patients with COPD, malnutrition is associated with impaired pulmonary status, decreased HRQoL and increased infections.<sup>4,10-12</sup> Body weight, BMI and muscle mass independently predict mortality and length of stay in people with COPD.<sup>4,9,12,14</sup>
- Nutritional supplementation in patients with COPD promotes weight gain and improves body composition, exercise tolerance, respiratory muscle strength, handgrip strength and HRQoL.<sup>10,11</sup>
- NICE recommends screening all patients for malnutrition risk.<sup>16</sup> Patients with COPD with low BMI should receive nutritional supplements.<sup>17</sup>
- High-protein nutritional supplements were associated with a reduced risk of complications, fewer hospital readmissions and increased handgrip strength.<sup>12</sup>
- The economic return associated with nutritional supplements are between 2 and 5 times greater than the investment.<sup>19</sup> Nutritional supplements reduced length of stay and readmission rates in patients hospitalised with COPD.<sup>7</sup>
- Fortisip Compact Protein is a high-energy, high-protein, ready to drink, nutritional supplement, for the dietary management of disease-related malnutrition including that associated with COPD.

## References

1. British Lung Foundation Chronic obstructive pulmonary disease (COPD) statistics Available at: <https://statistics.blf.org.uk/copd> Accessed June 2017.
2. NHS An Outcomes Strategy for COPD and Asthma: NHS Companion Document Published: 2012 Available at: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/216531/dh\\_134001.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216531/dh_134001.pdf) Accessed: June 2017.
3. Global Initiative for Chronic Obstructive Lung Disease (GOLD) Global Strategy for the Diagnosis, Management and Prevention of COPD Published: 2017. Available from: <http://goldcopd.org/gold-2017-global-strategy-diagnosis-management-prevention-copd/> Accessed June 2017.
4. Ezzell L and Jensen GL Malnutrition in chronic obstructive pulmonary disease. *The American Journal of Clinical Nutrition* 2000;72:1415-1416.
5. Schols AMWJ Nutritional and metabolic modulation in chronic obstructive pulmonary disease management. *European Respiratory Journal* 2003;22:81s-86s.
6. Rodríguez-Rodríguez E, Ortega RM, Andrés P *et al.* Antioxidant status in a group of institutionalised elderly people with chronic obstructive pulmonary disease. *British Journal of Nutrition* 2016;115:1740-1747.
7. Broekhuizen R, Creutzberg EC, Welings-Scheepers CAPM *et al.* Optimizing oral nutritional drink supplementation in patients with chronic obstructive pulmonary disease. *British Journal of Nutrition* 2005;93:965-971.
8. Collins PF, Stratton RJ, Kurukulaaratchy R *et al.* Prevalence of malnutrition in outpatients with chronic obstructive pulmonary disease. *Proceedings of the Nutrition Society* 2010;69:E147.
9. Steer J, Norman E, Gibson GJ *et al.* Comparison of indices of nutritional status in prediction of in-hospital mortality and early readmission of patients with acute exacerbations of COPD. *Thorax* 2010;65:A127 (P117)
10. Ferreira I, Brooks D, White J *et al.* Nutritional supplementation for stable chronic obstructive pulmonary disease. *Cochrane Database of Systematic Reviews* 2012;DOI: 10.1002/14651858.CD000998.pub3.
11. Collins PF, Elia M, and Stratton RJ Nutritional support and functional capacity in chronic obstructive pulmonary disease: A systematic review and meta-analysis. *Respirology* 2013;18:616-629.
12. Cawood AL, Elia M, and Stratton RJ Systematic review and meta-analysis of the effects of high protein oral nutritional supplements. *Ageing Research Reviews* 2012;11:278-296.
13. Rothnie KJ, Mullerova H, Thomas SL *et al.* Recording of hospitalizations for acute exacerbations of COPD in UK electronic health care records. *Clin Epidemiol* 2016;8:771-782.
14. Hoong JM, Ferguson M, Hukins C *et al.* Economic and operational burden associated with malnutrition in chronic obstructive pulmonary disease. *Clinical Nutrition* 2017;36:1105-1109.
15. Hallin R, Koivisto-Hursti U-K, Lindberg E *et al.* Nutritional status, dietary energy intake and the risk of exacerbations in patients with chronic obstructive pulmonary disease (COPD). *Respiratory Medicine* 2006;100:561-567.
16. National Institute for health and Care Excellence (NICE) Nutrition support in adults: oral nutrition support, enteral tube feeding and parental nutrition (Clinical Guideline 32) Published 2006 Available at: [www.nice.org.uk/guidance/cg32?unlid=823345483201681319620](http://www.nice.org.uk/guidance/cg32?unlid=823345483201681319620) Accessed: June 2017.
17. NICE Chronic obstructive pulmonary disease in over 16s: diagnosis and management (NG115), December 2018. Available at: <https://www.nice.org.uk/guidance/NG115> Accessed: December 2018.
18. British Lung Foundation Estimating the economic burden of respiratory illness in the UK Published: 2017 Available at: <https://www.blf.org.uk/what-we-do/our-research/economic-burden> Accessed: June 2017.
19. Elia M The cost of malnutrition in England and potential cost savings from nutritional interventions Published 2015 Available at: [www.bapen.org.uk/pdfs/economic-report-full.pdf](http://www.bapen.org.uk/pdfs/economic-report-full.pdf) Accessed June 2017.
20. Snider JT, Jena AB, Linthicum MT *et al.* Effect of hospital use of oral nutritional supplementation on length of stay, hospital cost, and 30-day readmissions among medicare patients with COPD. *Chest* 2015;147:1477-1484.
21. Pfeffer PE and Hawrylowicz CM Vitamin D and lung disease. *Thorax* 2012;67:1018-1020.