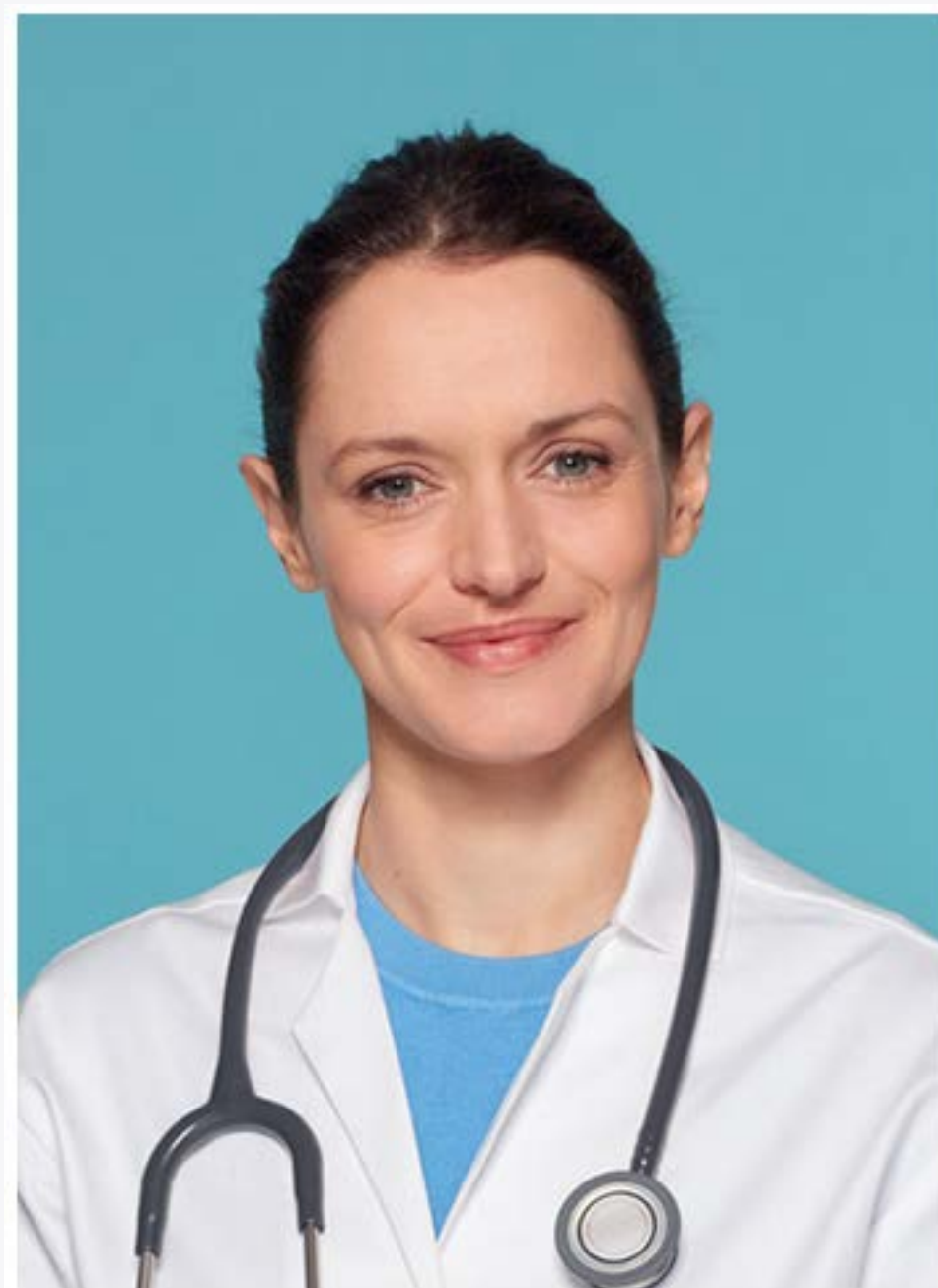


Introducing ModuLife, an innovative dietary management solution for Crohn's Disease



THERE'S NO OTHER TREATMENT FOR CROHN'S DISEASE LIKE IT

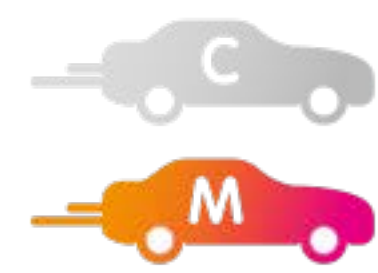
FOR HEALTHCARE PROFESSIONALS ONLY

DIET IS RECOMMENDED AS FIRST-LINE THERAPY FOR CHILDREN WITH CROHN'S DISEASE



EEN

Guidelines recommend exclusive enteral nutrition (EEN) due to its proven efficacy, safety and tolerability in children with CD.*¹⁻³



EEN induces remission as well as corticosteroids⁴



Effective in ~80% of patients¹



Increases the child's growth rate¹



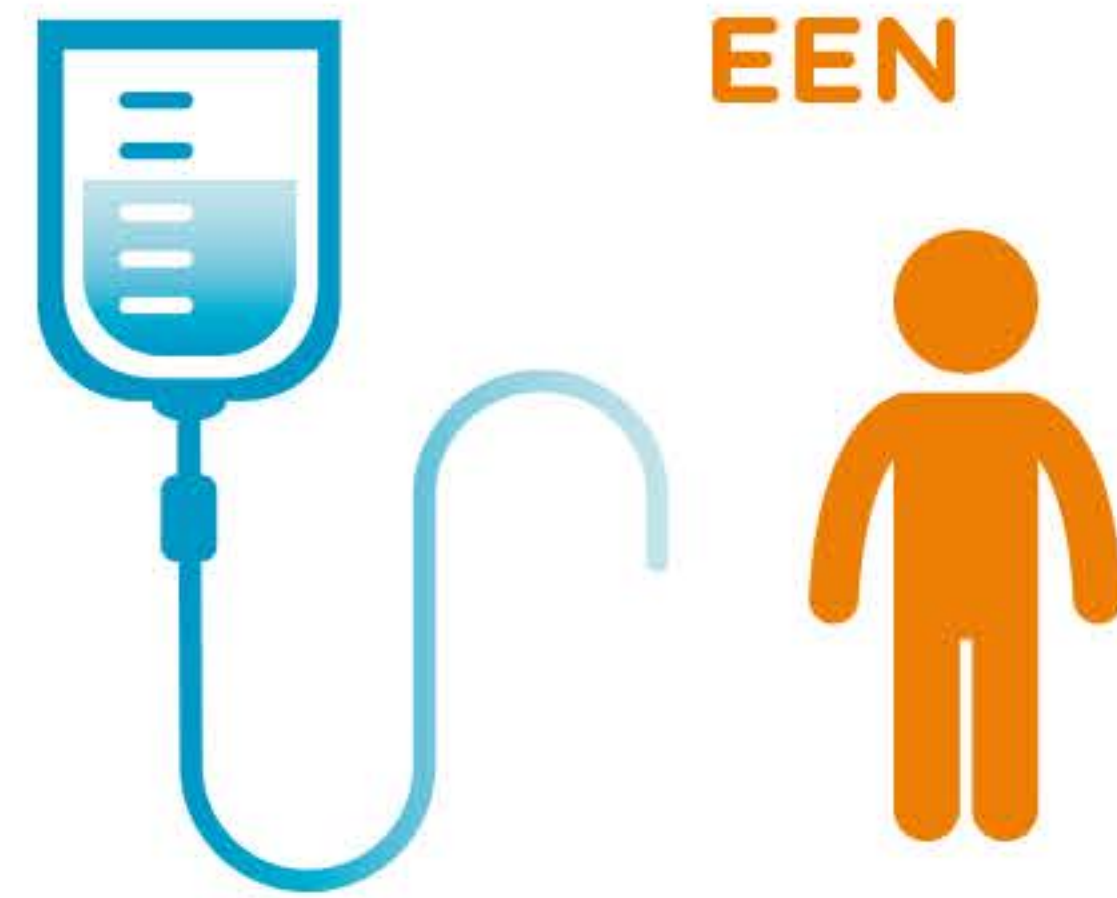
Well tolerated, especially polymeric feeds¹



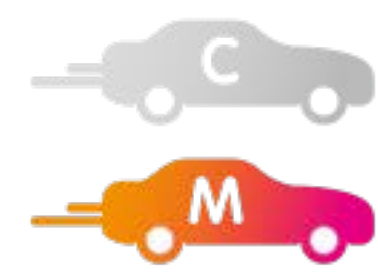
* Except in severe isolated Crohn's pancolitis

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1. Ruemmele FM *et al.* Consensus guidelines of ECCO/ESPGHAN on the medical management of pediatric Crohn's disease. *J Crohns Colitis*. 2014;8:1179-1207.
2. Day AS and Lopez RN. Exclusive enteral nutrition in children with crohn's disease. *World J Gastro*. 2015;21(22):6809-6816.
3. Miele E *et al.* Nutrition in Pediatric Inflammatory Bowel Disease: A Position Paper on Behalf of the Porto Inflammatory Bowel Disease Group of the ESPGHAN. *J Pediatr Gastroenterol Nutr*. 2018;66(4):687-708.
4. Borrelli O *et al.* Polymeric diet alone versus corticosteroids in the treatment of active pediatric Crohn's disease: a randomized controlled open-label trial. *Clin Gastroenterol Hepatol*. 2006 Jun;4(6):744-53.

ents¹

with rate¹

polymeric feeds¹

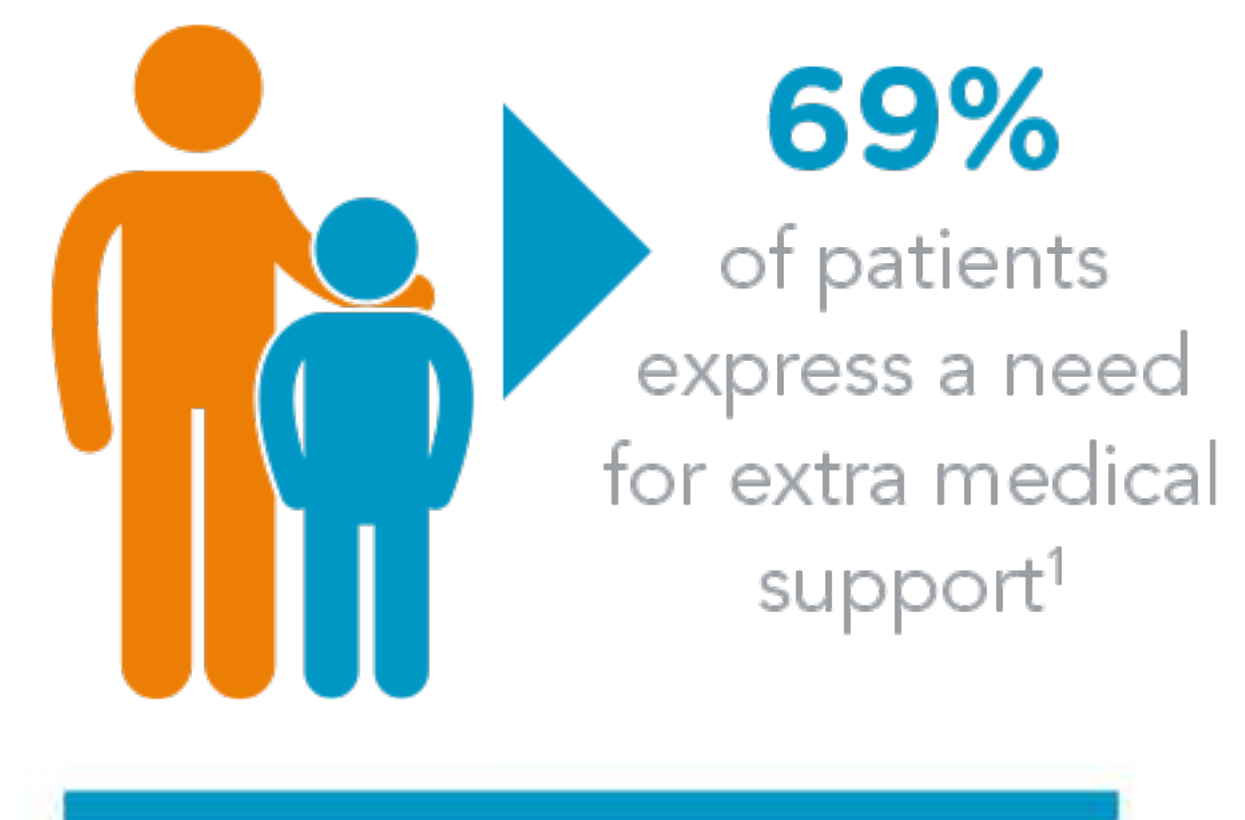
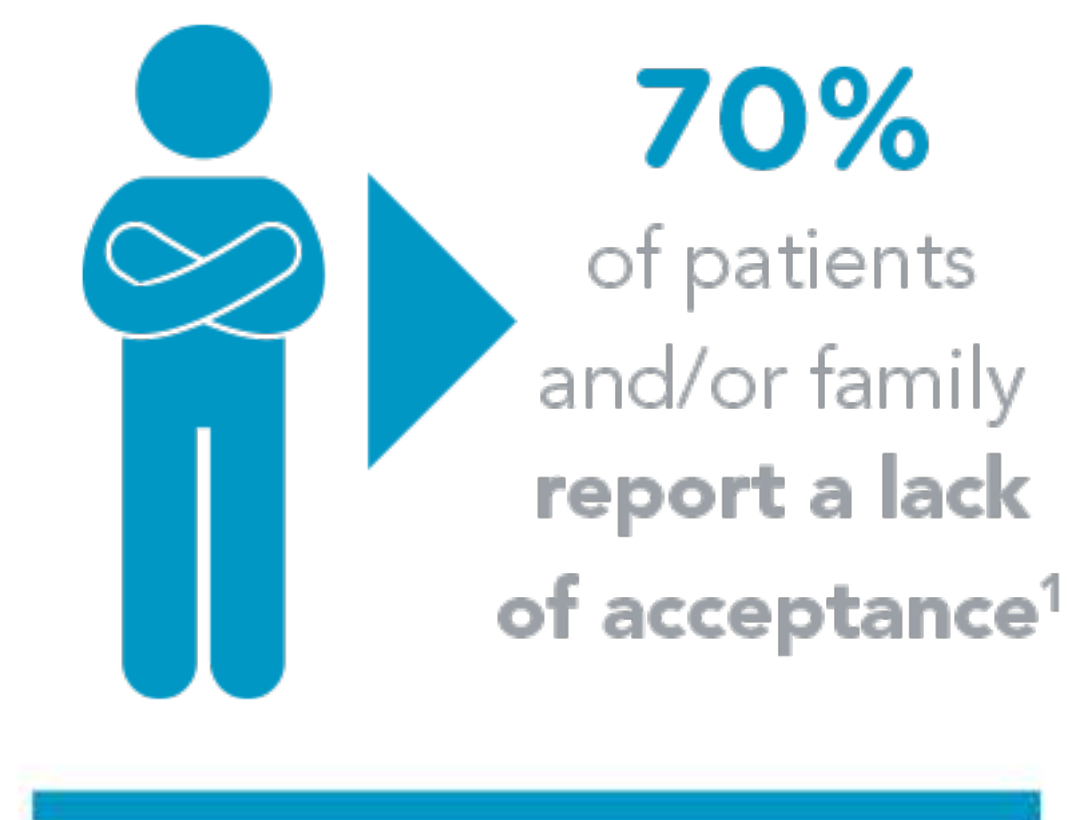
* Except in severe isolated Crohn's pancolitis



EEN POSES ACCEPTANCE CHALLENGES



Despite clinical advantages, EEN is not easily adopted by patients and caregivers¹



Reported adherence rates for EEN therapy: 84 to 92%²⁻⁶



EEN POSES ACCEPTANCE CHALLENGES



Despite clinical advantages, EEN is not easily adopted by patients and caregivers¹



70%
of patients



69%
of patients
express a need
for extra medical
support¹

1. Navas-López VM *et al.* PRESENT; Prescription of Enteral Nutrition in pediatric Crohn's disease in Spain. *Nutr Hosp.* 2014;29(3):537-46.
2. Kim HJ *et al.* Therapeutic Efficacy of Oral Enteral Nutrition in Pediatric Crohn's Disease: A Single Center Non-Comparative Retrospective Study. *Yonsei Med J.* 2016;57(5):1185-1191.
3. Rubio A *et al.* The efficacy of exclusive nutritional therapy in paediatric Crohn's disease, comparing fractionated oral vs. continuous enteral feeding. *Aliment Pharmacol Ther.* 2011;33(12):1332-1139.
4. Rodrigues AF *et al.* Does polymeric formula improve adherence to liquid diet therapy in children with active Crohn's disease? *Arch Dis Child.* 2007;92(9):767-770.
5. de Bie C *et al.* Use of exclusive enteral nutrition in paediatric Crohn's disease in The Netherlands. *J Crohns Colitis.* 2013;7(4):263-270.
6. Day AS *et al.* Exclusive enteral feeding as primary therapy for Crohn's disease in Australian children and adolescents: A feasible and effective approach. *J Gastroenterol Hepatol.* 2006;21(10):1609-1614.

43%

are not convinced
of treatment
suitability¹

therapy: 84 to 92%²⁻⁶



THE CROHN'S DISEASE EXCLUSION DIET (CDED) WITH PARTIAL ENTERAL NUTRITION (PEN)



The CDED coupled with PEN is the first and only whole food-based dietary approach proven to be effective in CD management¹

PHASE 1

50% allowed food list & 50% of TE[†] with Modulen® IBD



PHASE 2

75% expanded food list & 25% of TE[†] with Modulen® IBD



Maintenance Phase

75% expanded food list with 1 to 2 free days/week & 25% of TE[†] with Modulen® IBD



† TE = Total Energy

FOR HEALTHCARE PROFESSIONALS ONLY

THE CROHN'S DISEASE EXCLUSION DIET (CDED) WITH PARTIAL ENTERAL NUTRITION (PEN)



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Maintenance



1. Levine A *et al.* Evolving role of diet in the pathogenesis and treatment of inflammatory bowel diseases. *Gut*. 2018;66:1-13.

2. Levine A, Sigall-Boneh R, Wine E. Evolving role of diet in the pathogenesis and treatment of inflammatory bowel diseases *Gut*. 2018;66:1-13.



† TE = Total Energy

PRINCIPLES OF THE CDED + PEN



CDED + PEN was designed to induce and maintain remission, while ensuring palatability and long-term sustainability¹⁻³



Exclusion



Inclusion



Balanced



Progressive



PRINCIPLES OF THE CDED + PEN



CDED + PEN was designed to induce and maintain remission, while ensuring palatability and long-term sustainability¹⁻³



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3. Sigall-Boneh R *et al.* Partial enteral nutrition with a Crohn's disease exclusion diet is effective for induction of remission in children and young adults with Crohn's disease. *Inflamm Bowel Dis*. 2014;20(8):1353-60.





EXCLUSION OF FOODS KNOWN TO AFFECT THE HOST HEALTH AND/OR MICROBIOTA

- High fat (animal fat)
- Taurine (red meat)
- Dairy
- Wheat
- Alcohol
- Yeast
- Insoluble fibre

**COMMON FOOD
TO EXCLUDE**

- Emulsifiers
- Carrageenans
- Maltodextrins
- Sulfites
- Titanium Dioxide

**ADDITIVES
TO EXCLUDE**





PRINCIPLES OF THE CODED-FPEN

INCLUSION OF FOODS KNOWN TO PROMOTE REBIOSIS

The CODED-FPEN was designed to induce and maintain remission, while ensuring palatability and long-term sustainability.



Soluble fibre
(apple, banana)



Apple
pectin



Resistant starch
(potato, apple,
banana)



Healthy
microbiota



Improved barrier
function

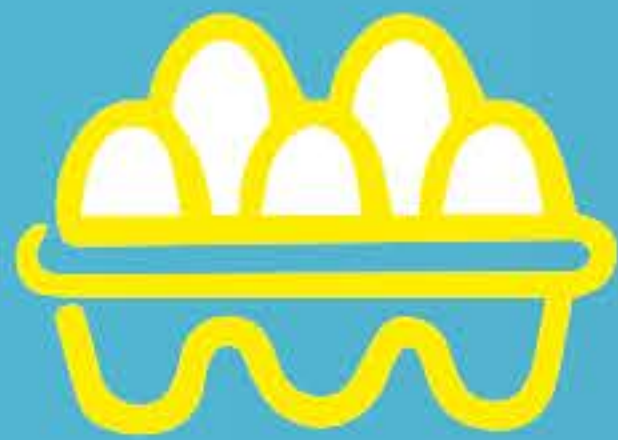




PRINCIPLES OF THE CDED-PEN

BALANCED DIET TO ENSURE ACCEPTANCE

CDED-PEN was designed to induce and maintain remission, while ensuring palatability and long-term sustainability.



Low-aurine proteins
(chicken breast,
egg, fish)



Healthy oils
(olive oil, canola oil)



Gluten-free
carbohydrates
(rice)



Fruits and vegetables
(orange, avocado,
lettuce...)



Complementary vitamins,
minerals & energy
(Modulen® IBD)





PROGRESSIVE DIET TO ENSURE PALATABILITY AND COMPLIANCE

Progressive Adaptable Modular Diet

Phase - 1
6 Weeks

Phase - 2
6 Weeks

More meat,
fruits and
vegetables

**Maintenance
Phase**

Bring back some
disallowed foods
with restrictions,
& 2 free days
per week



OFFERING HIGH REMISSION RATES



CDED with PEN showed equal efficacy but higher tolerability than Exclusive Enteral Nutrition (EEN) in a randomised controlled trial in paediatric patients with mild-to-moderate active CD¹

● Tolerance rate

97.5%
vs. 73.6% for EEN
($p=0.002$)¹



● Sustained remission rate at 12 weeks

75.6%
vs. 45.1% for EEN
($p=0.01$)¹



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DIETARY INTERVENTIONS IN THE PIVOTAL RANDOMISED CONTROLLED TRIAL

- Patients were randomised to a CDED + PEN or EEN arm[†]

CDED + PEN arm[†]

PHASE 1

50% allowed food list & 50% of TE[†] with Modulen[®] IBD



PHASE 2

75% expanded food list & 25% of TE[†] with Modulen[®] IBD



[†] TE = Total Energy

EEN arm[†]

PHASE 1

100% of TE[†] with Modulen[®] IBD



PHASE 2

75% free diet (gradual reintroduction for 1st three weeks) & 25% of TE[†] with Modulen[®] IBD



vs. 45.1% for EEN
(p=0.01)[†]



SUSTAINED REMISSION RATE AT 6 WEEKS

- CDED + PEN and EEN showed similar rates of corticosteroid-free remission at 6 weeks (PCDAI<10)¹



75.0%
vs. 58.8% for EEN
(p=NS*)¹

† TE = Total Energy

OFFERING HIGH REMISSION RATES



CDED with PEN induced remission in paediatric and adult patients with CD, including those who failed biological therapy^{1,2}

Most patients achieved remission after 6 weeks of CDED + PEN^{1,2}

70.2%

of patients with early mild-to-moderate luminal CD¹



61.9%

of patients with CD failing biological therapy²



OFFERING HIGH REMISSION RATES



CDED with PEN induced remission in paediatric and adult patients with CD, including those who failed biological therapy^{1,2}

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1.9%

patients with CD failing biological therapy²



DIETARY INTERVENTION IN PILOT TRIALS WITH CDED + PEN

- Patients followed the first two phases of CDED with PEN^{1,2}

PHASE 1

50% allowed food list & 50% of TE[†] with Modulen® IBD



PHASE 2

75% expanded food list & 25% of TE[†] with Modulen® IBD



† TE = Total Energy



ModuLife™ is designed to support you and your patients throughout the CDED + PEN journey.



MODULEN® IBD has extensive clinical evidence on symptom relief and mucosal healing when used as EEN therapy in paediatric CD



Expert platform with structured e-learning modules and tools for healthcare professionals



Support platform for patients to improve compliance

A COMPREHENSIVE DIETARY MANAGEMENT SOLUTION BASED ON CDED + PEN USING MODULEN® IBD AS SUPPORTIVE PEN FORMULA



FOR HEALTHCARE PROFESSIONALS ONLY

1. Afzal NA *et al.* Colonic Crohn's disease in children does not respond well to treatment with enteral nutrition if the ileum is not involved. *Dig Dis Sci.* 2005;50(8):1471-5.
2. Afzal NA *et al.* Improvement in quality of life of children with acute Crohn's disease does not parallel mucosal healing after treatment with exclusive enteral nutrition. *Aliment Pharmacol Ther.* 2004;20(2):167-72.
3. Borrelli O *et al.* Polymeric diet alone versus corticosteroids in the treatment of active pediatric Crohn's disease: a randomized controlled open-label trial. *Clin Gastroenterol Hepatol.* 2006;4(6):744-53.
4. Buchanan E *et al.* The use of exclusive enteral nutrition for induction of remission in children with Crohn's disease demonstrates that disease phenotype does not influence clinical remission. *Aliment Pharmacol Ther.* 2009;30(5):501-7.
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7. Fell JM *et al.* Mucosal healing and a fall in mucosal pro-inflammatory cytokine mRNA induced by a specific oral polymeric diet in paediatric Crohn's disease. *Aliment Pharmacol Ther.* 2000;14(3):281-9.
8. Frivolt K *et al.* Repeated exclusive enteral nutrition in the treatment of paediatric Crohn's disease: predictors of efficacy and outcome. *Aliment Pharmacol Ther.* 2014;39(12):1398- 407.
9. Gavin J *et al.* Energy intakes of children with Crohn's disease treated with enteral nutrition as primary therapy. *J Hum Nutr Diet.* 2005;18(5):337-42.
10. Gerasimidis K *et al.* Impact of exclusive enteral nutrition on body composition and circulating micronutrients in plasma and erythrocytes of children with active Crohn's disease. *Inflamm Bowel Dis.* 2012;18(9):1672-81.
11. Gerasimidis K *et al.* Serial fecal calprotectin changes in children with Crohn's disease on treatment with exclusive enteral nutrition: associations with disease activity, treatment response, and prediction of a clinical relapse. *J Clin Gastroenterol.* 2011;45(3):234-9.
12. Lionetti P *et al.* Enteral nutrition and microflora in pediatric Crohn's disease. *JPEN J Parenter Enteral Nutr.* 2005;29(4 Suppl):S173-5.
13. Logan M *et al.* A prospective cohort of patients receiving exclusive enteral nutrition (EEN) confirms high clinical response rates after 8 weeks of treatment: initial results from the BIG study. *J Ped Gastroenterol Nutr.* 2017; 64, (Suppl 1): 506 (abstract: G-P-283; presented as poster at the 50th Annual Meeting of ESPGHAN 2017, May 10-13, Prague, Czech Republic).
14. Navas López VM *et al.* [Efficacy of exclusive enteral feeding as primary therapy for paediatric Crohn's disease]. *An Pediatr (Barc).* 2008;69(6):506-14. (Article in Spanish).
15. Navas-López VM *et al.* [Exclusive enteral nutrition continues to be first line therapy for pediatric Crohn's disease in the era of biologics]. *An Pediatr (Barc).* 2015;83(1):47-54.
16. Phylactos AC *et al.* Effect of enteral nutrition on antioxidant enzyme systems and inflammation in paediatric Crohn's disease. *Acta Paediatr.* 2001;90(8):883-8.
17. Rubio A *et al.* The efficacy of exclusive nutritional therapy in paediatric Crohn's disease, comparing fractionated oral vs. continuous enteral feeding. *Aliment Pharmacol Ther.* 2011;33(12):1332-9.
18. Schwerdt T *et al.* Exclusive enteral nutrition in active pediatric Crohn disease: Effects on intestinal microbiota and immune regulation. *J Allergy Clin Immunol.* 2016;138(2):592-6.
19. Werkstetter KJ *et al.* Influence of exclusive enteral nutrition therapy on bone density and geometry in newly diagnosed pediatric Crohn's disease patients. *Ann Nutr Metab.* 2013;63(1-2):10-6.



MODULEN® IBD, PROVEN EFFICACY AS EXCLUSIVE ENTERAL NUTRITION

ModuleN® is designed to support you and your patients

- Modulen® IBD has extensive clinical evidence as first-line therapy in paediatric CD¹⁻¹⁹



Induces remission as effectively and as rapidly as corticosteroids³



Superior mucosal healing vs corticosteroids³



Positively impacts linear growth^{3,4,17}

COMPREHENSIVE DIETARY MANAGEMENT SOLUTION BASED ON
EXCLUSIVE ENTERAL NUTRITION USING MODULEN® AS SUPPORTIVE FEEDING FORMULA



EXPERT TRAINING

- Expert platform with structured e-learning modules



- Register and get access to our exclusive online e-learning modules dedicated to understanding the principles of the CDED with PEN and the clinical data in support of this novel dietary approach
- Gain the skills you need to become a certified ModuLife expert (successful completion of 4 modules)
- Get access to support tools for your patients



www.modulifexpert.com



PATIENT SUPPORT

- A unique patient platform to improve compliance



After invitation by a ModuLife expert, your patients get to:

- Access a large selection of CDED-friendly recipes and meal plans
- Track their food intake, daily physical activity and well-being
- Receive advice to improve physical and mental well-being

Recommend ModuLife to paediatric patients with mild-to-moderate active Crohn's Disease having difficulties with EEN



- Based on the clinically proven dietary therapy: CDED coupled with PEN (Modulen® IBD)
- A comprehensive programme for you and your patients
- Access to a unique website, training and mobile app
- Patient support programme



Register today on

▶ <https://modulifexpert.com/Register>

to become a certified expert



THERE'S NO OTHER TREATMENT FOR CROHN'S DISEASE LIKE IT

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FOR HEALTHCARE PROFESSIONALS ONLY

“DOCTOR, WHAT SHOULD I BE EATING?”



A large number of adult patients with Crohn's Disease (CD) are worried about their diet:^{1,2}

77% of patients avoid eating certain foods.³

62% of patients believe that diet influences the disease course.³

59% of patients value nutrition to be equally or more important than medication.³

Being able to partake in social events or share a meal contributes to patients' quality of life and well-being¹



“DOCTOR, WHAT SHOULD I BE EATING?”



A large number of adult patients with Crohn's Disease (CD) are worried about their diet:^{1,2}

77% of patients avoid eating certain foods.³

62% of patients believe that diet influences the disease course.³

59% of patients value nutrition to be equally or more important than medication.³

1. Kane S. What physicians don't know about patient dietary beliefs and behavior can make a difference. *Expert Rev Gastroenterol Hepatol*. 2012;6(5):545-7.

2. Zallot C *et al*. Dietary beliefs and behavior among inflammatory bowel disease patients. *Inflamm Bowel Dis*. 2013;19(1):66-72.

3. De Vries JHM *et al*. Patient's dietary beliefs and behaviours in inflammatory bowel disease. *Dig Dis*. 2019;37(2):131-139.

social events
s to patients'
ng¹



HOW DIET IMPACTS THE PATHOGENESIS OF CROHN'S DISEASE



Heredity explains only up to **26% of CD pathogenesis**^{1,2}



Accepted link between the **Western diet and CD incidence**¹



Diet is an **adjunct therapy** for treatment of adult CD³

There is a need for a complete management strategy to tackle the complexity of CD



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Heredity explains only up to **26% of CD pathogenesis**^{1,2}



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2. Peters LA *et al.* A functional genomics predictive network model identifies regulators of inflammatory bowel disease. *Nat Genet*. 2017;49(10):1437-1449.
3. Lichtenstein GR *et al.* ACG Clinical Guideline: Management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113(4):481-517.

Optimal management
of complexity of CD



THE CROHN'S DISEASE EXCLUSION DIET (CDED) WITH PARTIAL ENTERAL NUTRITION (PEN)



The CDED coupled with PEN is the first and only whole food-based dietary approach proven to be effective in CD management¹

PHASE 1

50% allowed food list & 50% of TE⁺ with Modulen® IBD



PHASE 2

75% expanded food list & 25% of TE⁺ with Modulen® IBD



Maintenance Phase

75% expanded food list with 1 to 2 free days/week & 25% of TE⁺ with Modulen® IBD



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Maintenance Phase

75% expanded



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PRINCIPLES OF THE CDED + PEN



CDED + PEN was designed to induce and maintain remission, while ensuring palatability and long-term sustainability¹⁻³



Exclusion



Inclusion



Balanced



Progressive



PRINCIPLES OF THE CDED + PEN



CDED + PEN was designed to induce and maintain remission, while ensuring palatability and long-term sustainability¹⁻³



Exclusion



Inclusion

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EXCLUSION OF FOODS KNOWN TO AFFECT THE HOST HEALTH AND/OR MICROBIOTA

• The diet was designed to induce and maintain remission.

- High fat (animal fat)
- Taurine (red meat)
- Dairy
- Wheat
- Alcohol
- Yeast
- Insoluble fibre

**COMMON FOOD
TO EXCLUDE**

- Emulsifiers
- Carrageenans
- Maltodextrins
- Sulfites
- Titanium Dioxide

**ADDITIVES
TO EXCLUDE**





INCLUSION OF FOODS KNOWN TO PROMOTE REBIOSIS

CDSS + PPA was designed to induce and maintain remission,



Soluble fibre
(apple, banana)



Apple
pectin



Resistant starch
(potato, apple,
banana)



**Healthy
microbiota**

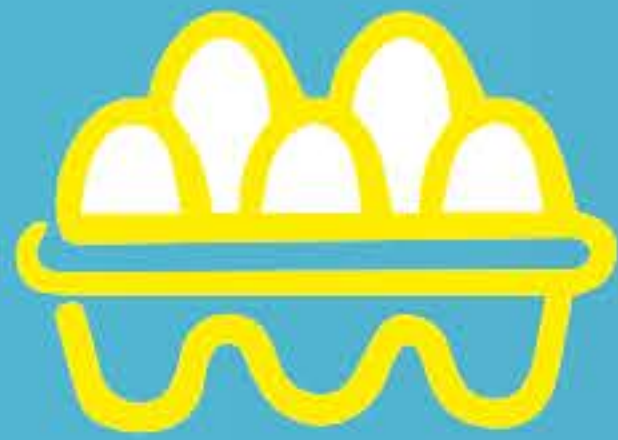


**Improved barrier
function**



BALANCED DIET TO ENSURE ACCEPTANCE

CDED + PPN was designed to induce and maintain remission,



Low-aurine proteins
(chicken breast,
egg, fish)



Healthy oils
(olive oil, canola oil)



Gluten-free
carbohydrates
(rice)



Fruits and vegetables
(orange, avocado,
lettuce...)



Complementary vitamins,
minerals & energy
(Modulen® IBD)





PRINCIPLES OF THE FODMAP DIET

PROGRESSIVE DIET TO ENSURE PALATABILITY AND COMPLIANCE

CDD & PDD was designed to induce and maintain remission,

Progressive Adaptable Modular Diet

**Phase - 1
6 Weeks**

**Phase - 2
6 Weeks**

More meat,
fruits and
vegetables

**Maintenance
Phase**

Bring back some
disallowed foods
with restrictions,
& 2 free days
per week



OFFERING HIGH REMISSION RATES



CDED with PEN has been shown to induce remission in adult and paediatric patients with CD¹⁻³

Most adult patients achieved remission after 6 weeks of CDED + PEN^{1,2}

69%

of adults with early mild-to-moderate luminal CD¹

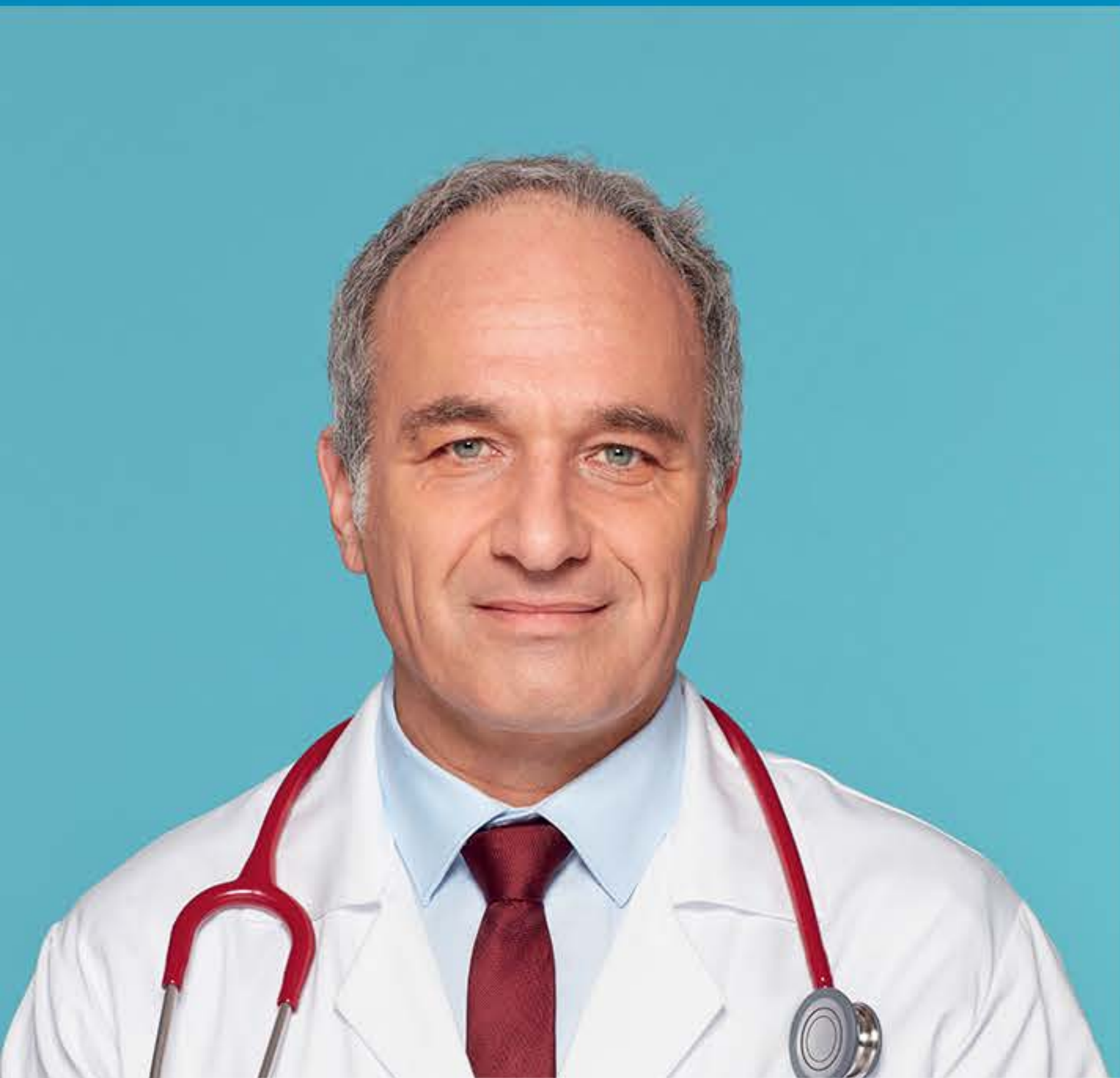


64%

of adults with CD failing biological therapy²



OFFERING HIGH REMISSION RATES



CDED with PEN has been shown to induce remission in adult and paediatric patients with CD¹⁻³

Most adult patients achieved remission after 6 weeks of CDED + PEN^{1,2}

69%
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4%
adults with CD failing
biological therapy²



DIETARY INTERVENTION IN PILOT TRIALS WITH CDED + PEN

- Patients followed the first two phases of CDED with PEN^{1,2}

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50% allowed food list & 50% of TE[†] with Modulen® IBD



PHASE 2

75% expanded food list & 25% of TE[†] with Modulen® IBD



† TE = Total Energy

OFFERING HIGH TOLERABILITY AND REMISSION RATES



CDED with PEN showed equal efficacy but higher tolerability than Exclusive Enteral Nutrition (EEN) in a randomised controlled trial in paediatric patients with mild-to-moderate active CD¹

- Tolerance rate

97.5%

vs. 73.6% for EEN
($p=0.002$)¹



- Sustained remission rate at 12 weeks



75.6%

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OFFERING HIGH TOLERABILITY AND REMISSION RATES



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DIETARY INTERVENTIONS IN THE PIVOTAL RANDOMISED CONTROLLED TRIAL

- Patients were randomised to a CDED + PEN or EEN arm¹

CDED + PEN arm¹

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50% allowed food list & 50% of TE[†] with Modulen[®] IBD



PHASE 2

75% expanded food list & 25% of TE[†] with Modulen[®] IBD



EEN arm¹

PHASE 1

100% of TE[†] with Modulen[®] IBD



PHASE 2

75% free diet (gradual reintroduction for 1st three weeks) & 25% of TE[†] with Modulen[®] IBD



† TE = Total Energy

vs. 45.1% for EEN
(p=0.01)¹



SUSTAINED REMISSION RATE AT 6 WEEKS

- CDED + PEN and EEN showed similar rates of corticosteroid-free remission at 6 weeks (PCDAI < 10)¹



75.0%
vs. 58.8% for EEN
(p=NS*)¹

† TE = Total Energy



ModuLife™ is designed to support you and your patients throughout the CDED + PEN journey.



MODULEN® IBD has extensive clinical evidence on symptom relief and mucosal healing when used as EEN therapy in paediatric CD



Expert platform with structured e-learning modules and tools for healthcare professionals



Support platform for patients to improve compliance

A COMPREHENSIVE DIETARY MANAGEMENT SOLUTION BASED ON CDED + PEN USING MODULEN® IBD AS SUPPORTIVE PEN FORMULA



FOR HEALTHCARE PROFESSIONALS ONLY

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MODULEN® IBD, PROVEN EFFICACY AS EXCLUSIVE ENTERAL NUTRITION

ModuleN® is designed to support you and your patients

- Modulen® IBD has extensive clinical evidence as first-line therapy in paediatric CD¹⁻¹⁹



Induces remission as effectively and as rapidly as corticosteroids³



Superior mucosal healing vs corticosteroids³



Positively impacts linear growth^{3,4,17}



EXPERT TRAINING

- Expert platform with structured e-learning modules



- Register and get access to our exclusive online e-learning modules dedicated to understanding the principles of the CDED with PEN and the clinical data in support of this novel dietary approach
- Gain the skills you need to become a certified ModuLife expert (successful completion of 4 modules)
- Get access to support tools for your patients



www.modulifexpert.com



PATIENT SUPPORT

- A unique patient platform to improve compliance



After invitation by a ModuLife expert, your patients get to:

- Access a large selection of CDED-friendly recipes and meal plans
- Track their food intake, daily physical activity and well-being
- Receive advice to improve physical and mental well-being

Recommend ModuLife to adult patients with Crohn's Disease interested in diet and disease management



- Based on the clinically proven dietary therapy: CDED coupled with PEN (Modulen® IBD)
- A comprehensive programme for you and your patients
- Access to a unique website, training and mobile app
- Patient support programme



Register today on

▶ <https://modulifexpert.com/Register>

to become a certified expert



THERE'S NO OTHER TREATMENT FOR CROHN'S DISEASE LIKE IT

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