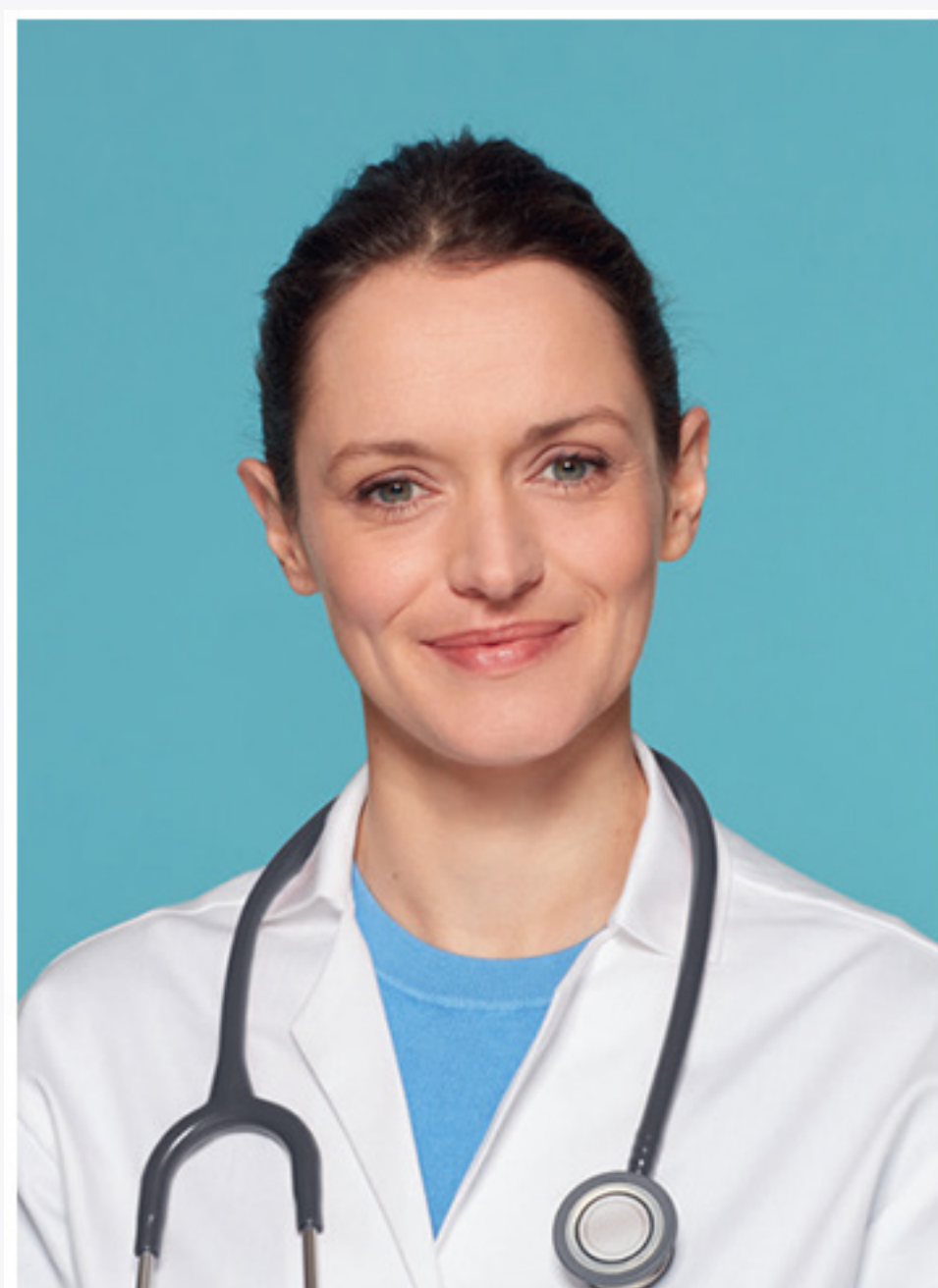




This is an
INTERACTIVE
document with
buttons to help
you navigate to
the information
you need

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



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

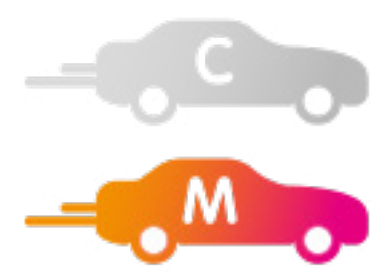
FOR HEALTHCARE PROFESSIONALS ONLY

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



EEN

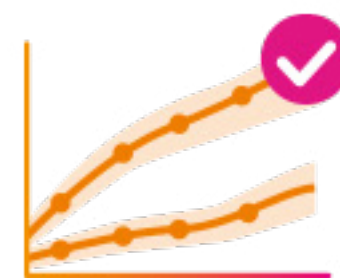
Guidelines recommend exclusive enteral nutrition (EEN) due to its proven efficacy, safety and tolerability in children with CD.*¹⁻³



EEN induces remission as well as corticosteroids⁴



Effective in ~80% of patients¹



Increases the child's growth rate¹



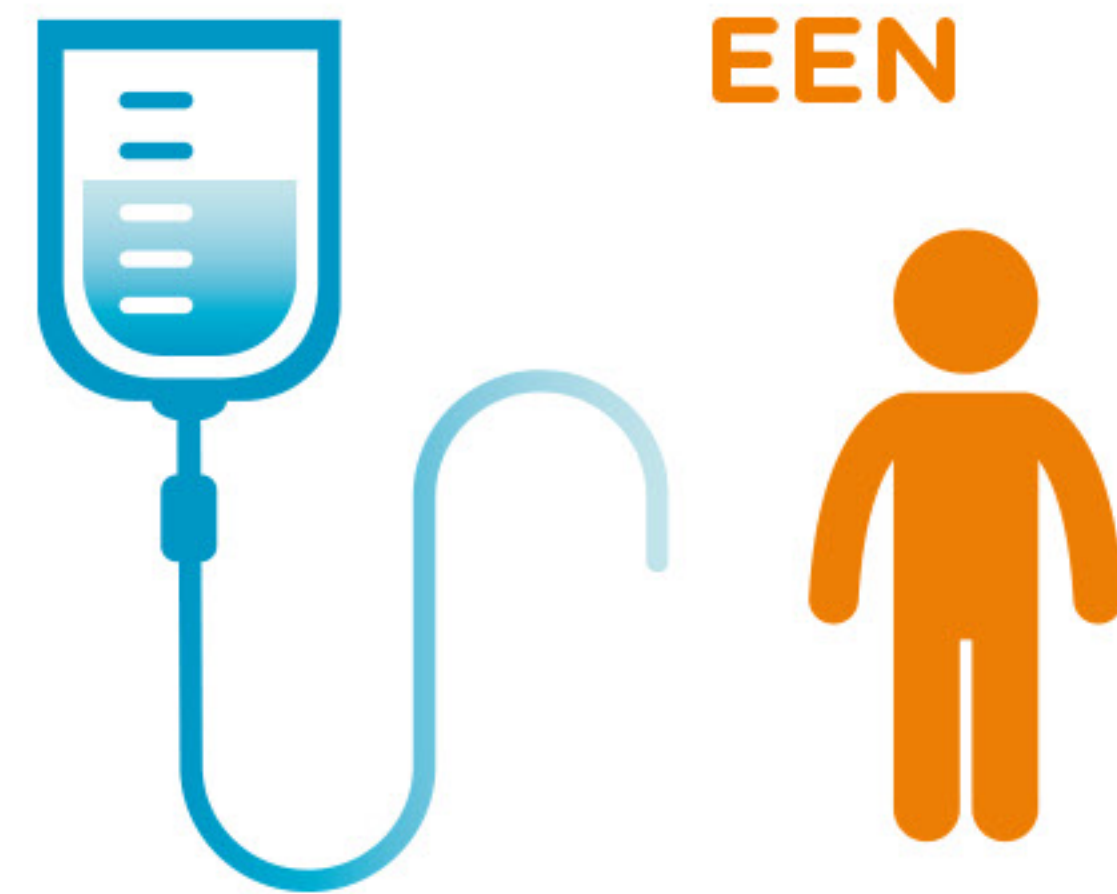
Well tolerated, especially polymeric feeds¹



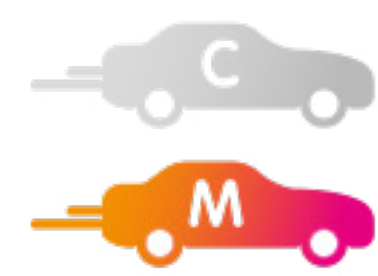
* Except in severe isolated Crohn's pancolitis

FOR HEALTHCARE PROFESSIONALS ONLY

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



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



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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.

* Except in severe isolated Crohn's pancolitis



ents¹

with rate¹

polymeric feeds¹

EEN POSES ACCEPTANCE CHALLENGES



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



70%
of patients
and/or family
**report a lack
of acceptance¹**



69%
of patients
express a need
for extra medical
support¹



43%
are not convinced
of treatment
suitability¹

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



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



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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

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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**

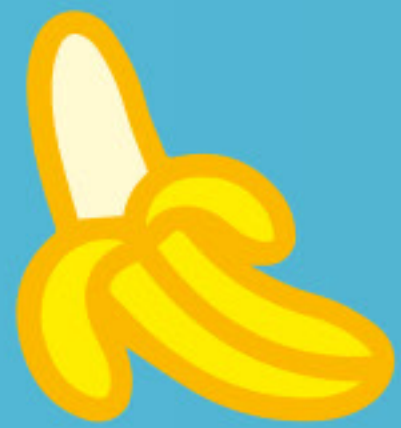




PRINCIPLES OF THE CODED-F-PEN

INCLUSION OF FOODS KNOWN TO PROMOTE REBIOSIS

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



Soluble fibre
(apple, banana)



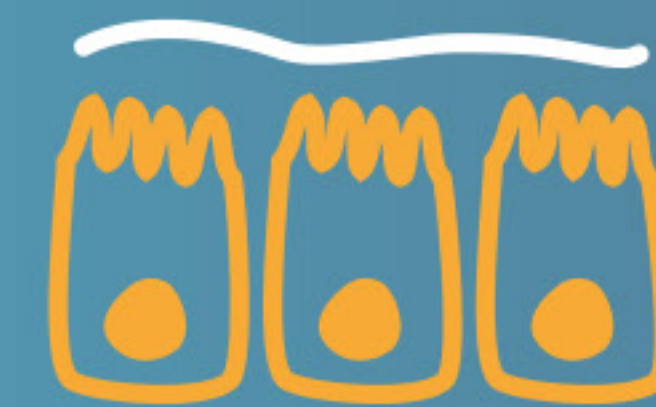
Apple
pectin



Resistant starch
(potato, apple,
banana)



**Healthy
microbiota**



**Improved barrier
function**

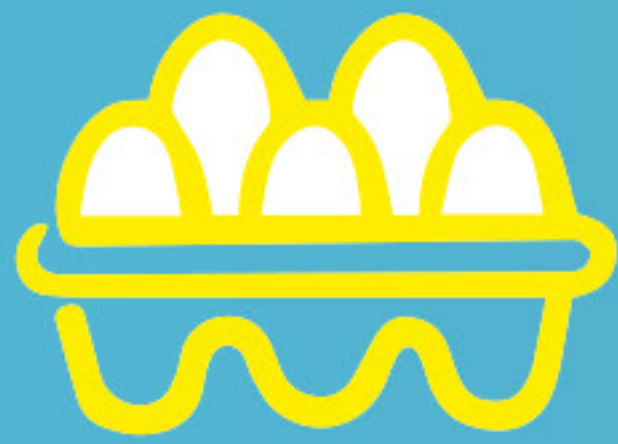




PRINCIPLES OF THE CODED-PEN

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)





PRINCIPLES OF THE ECODED OPEN

PROGRESSIVE DIET TO ENSURE PALATABILITY AND COMPLIANCE

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

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 arm¹

CDED + PEN arm¹

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 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



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

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



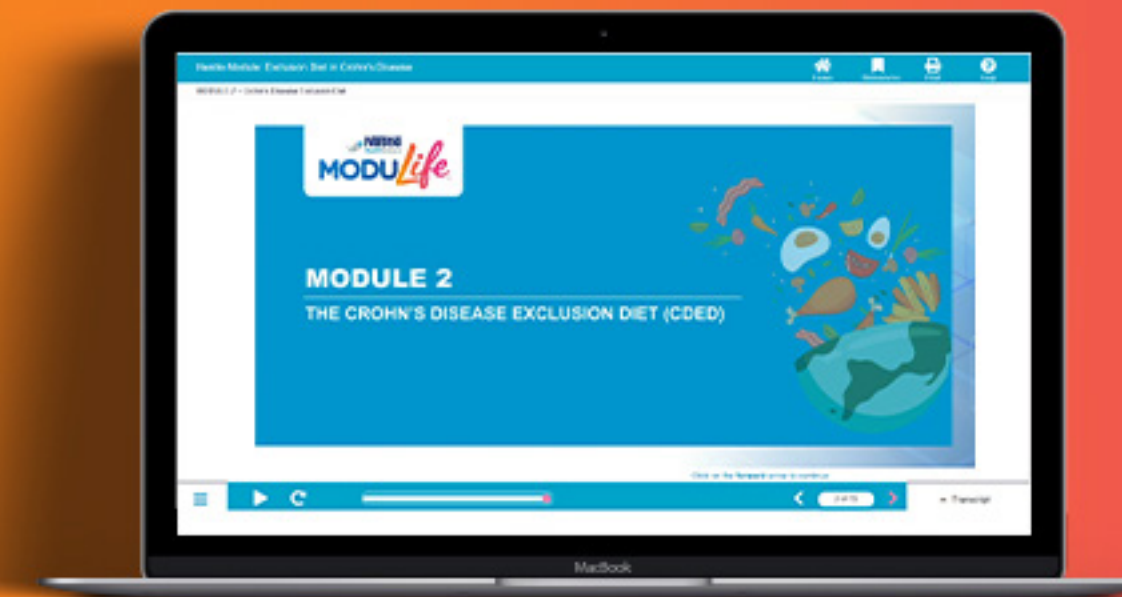
† TE = Total Energy



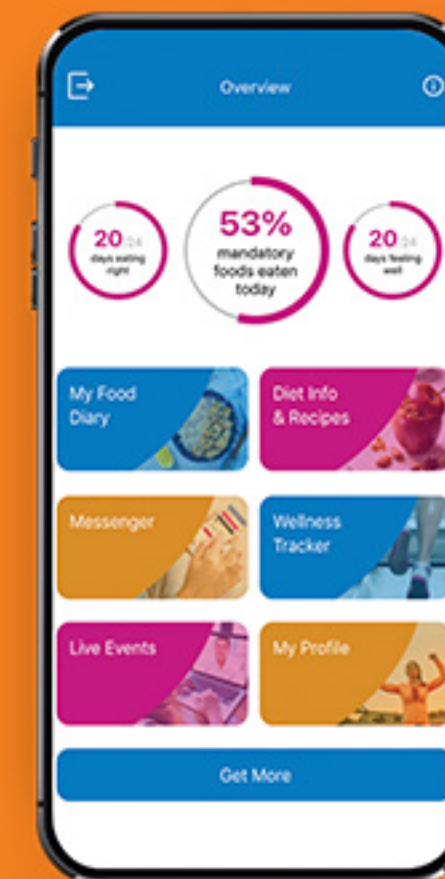
ModuLife™ is designed to support you and your patients throughout the CDED + PEN journey.



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



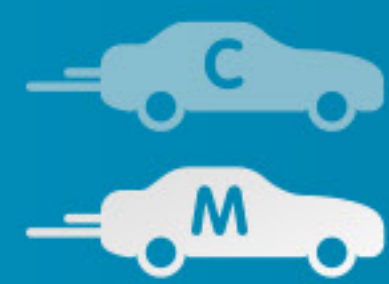
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1. Afzal NA *et al.* Colonic Crohn's disease in children does not respond well to treatment with enteral nutrition if the ileum is not involved. *Dig Dis Sci.* 2005;50(8):1471-5.
2. Afzal NA *et al.* Improvement in quality of life of children with 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.
5. Cameron FL *et al.* Clinical progress in the two years following a course of exclusive enteral nutrition in 109 paediatric patients with Crohn's disease. *Aliment Pharmacol Ther.* 2013;37(6):622-9.
6. Faïman A *et al.* Standard versus rapid food reintroduction after exclusive enteral nutritional therapy in paediatric Crohn's disease. *Eur J Gastroenterol Hepatol.* 2014;26(3):276-81.
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.
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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).
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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.
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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

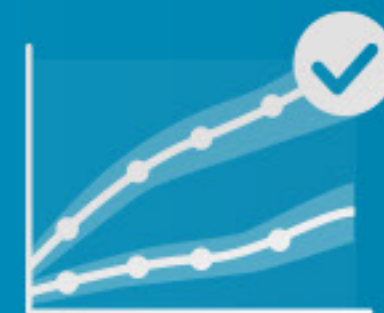
- Modulen® IBD has extensive clinical evidence as first-line therapy in paediatric CD¹⁻¹⁹



Induces remission as effectively and as rapidly as corticosteroids³



Superior mucosal healing vs corticosteroids³



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

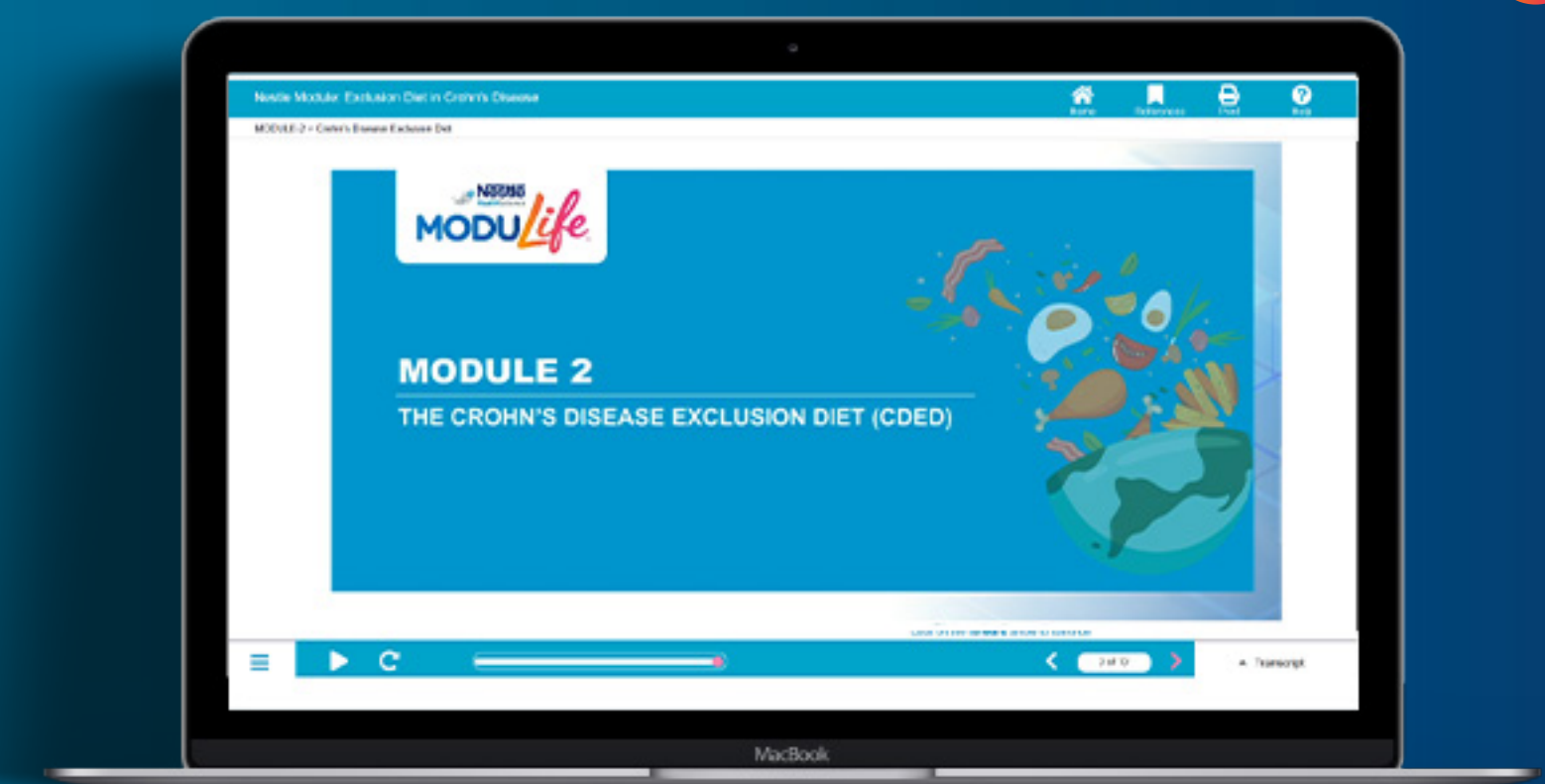


EXPERT TRAINING

- 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

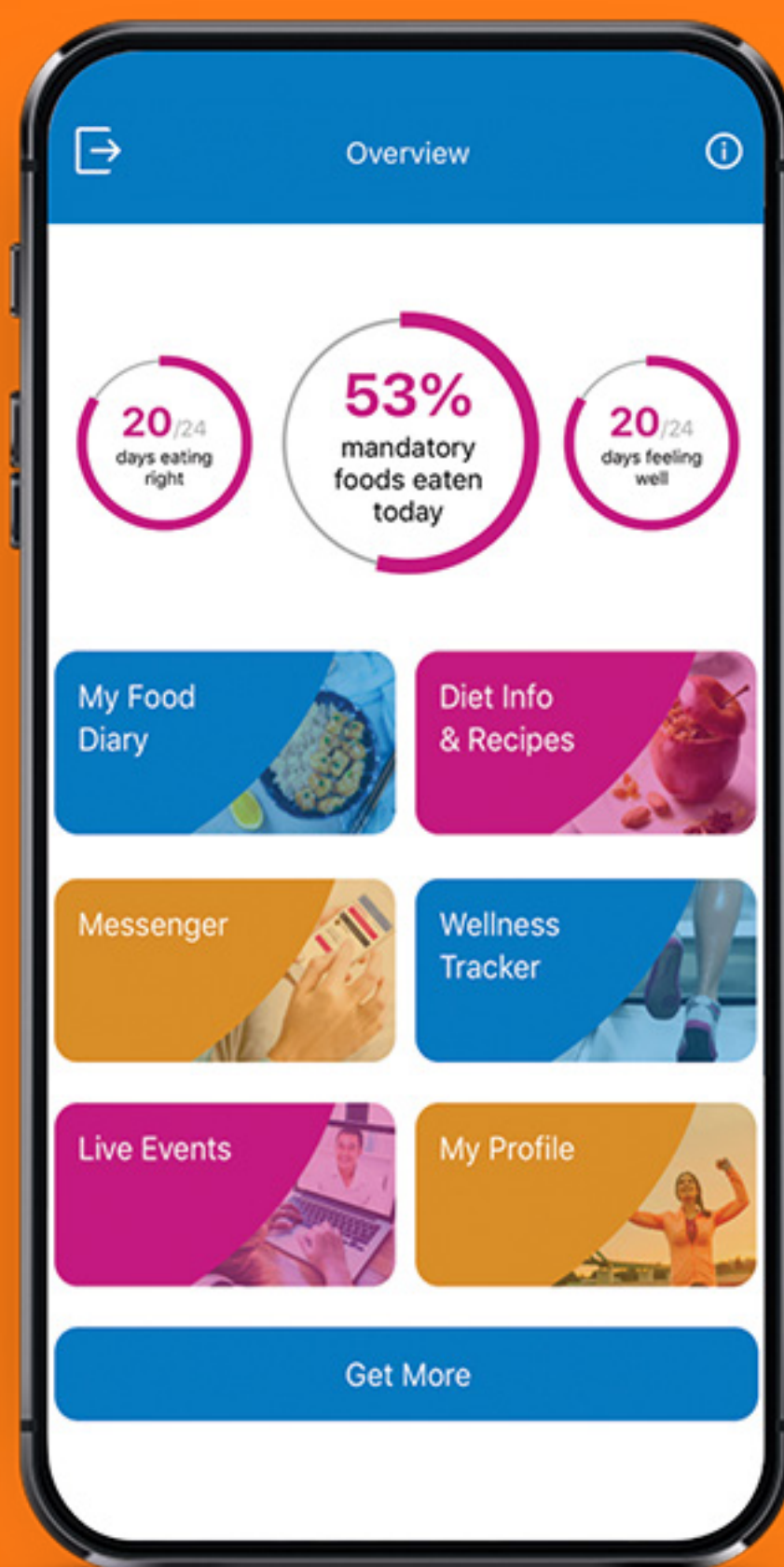


www.modulifexpert.com



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 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

“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

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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



HOW DIET IMPACTS THE PATHOGENESIS OF CROHN'S DISEASE



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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 the 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

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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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Aggressive





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

CDED + FEN 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

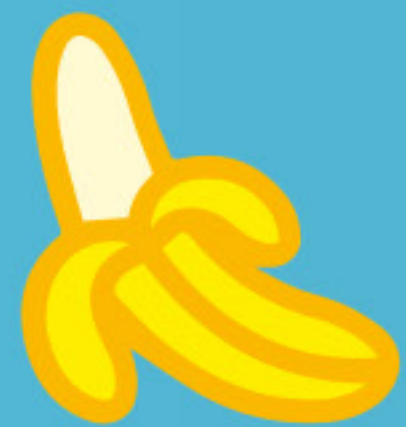
**ADDITIVES
TO EXCLUDE**





INCLUSION OF FOODS KNOWN TO PROMOTE REBIOSIS

CDED + PEN was designed to induce and maintain remission,



Soluble fibre
(apple, banana)



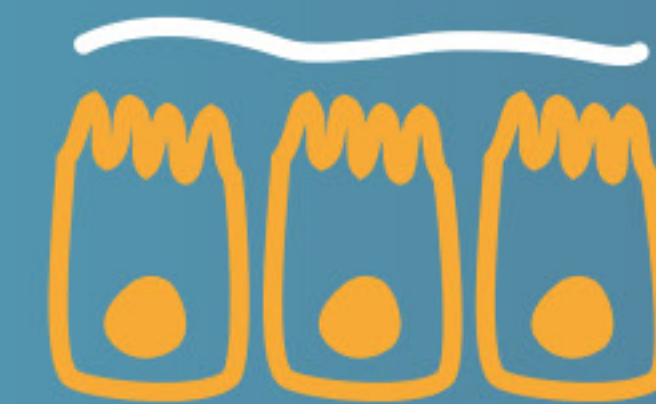
Apple
pectin



Resistant starch
(potato, apple,
banana)



Healthy
microbiota



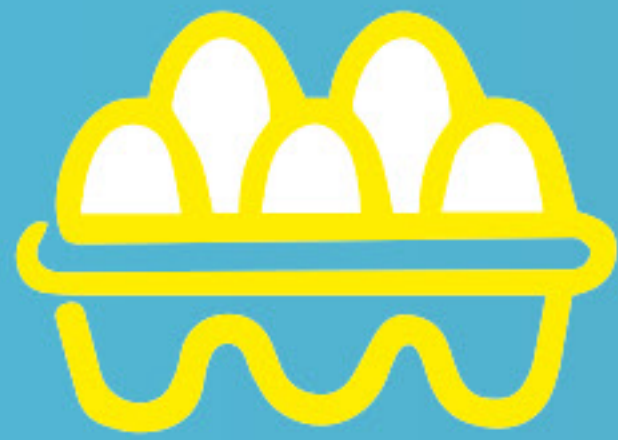
Improved barrier
function





BALANCED DIET TO ENSURE ACCEPTANCE

CDED + PEN was designed to induce and maintain remission,



Low-taurine 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

CDED + PCD 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



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luminal CD¹



1. 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.

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3. Levine A *et al.* Crohn's Disease Exclusion Diet Plus Partial Enteral Nutrition Induces Sustained Remission in a Randomized Controlled Trial. *Gastroenterology.* 2019;157(2):440-450.

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}

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

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%

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 arm¹

CDED + PEN arm¹

PHASE 1

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

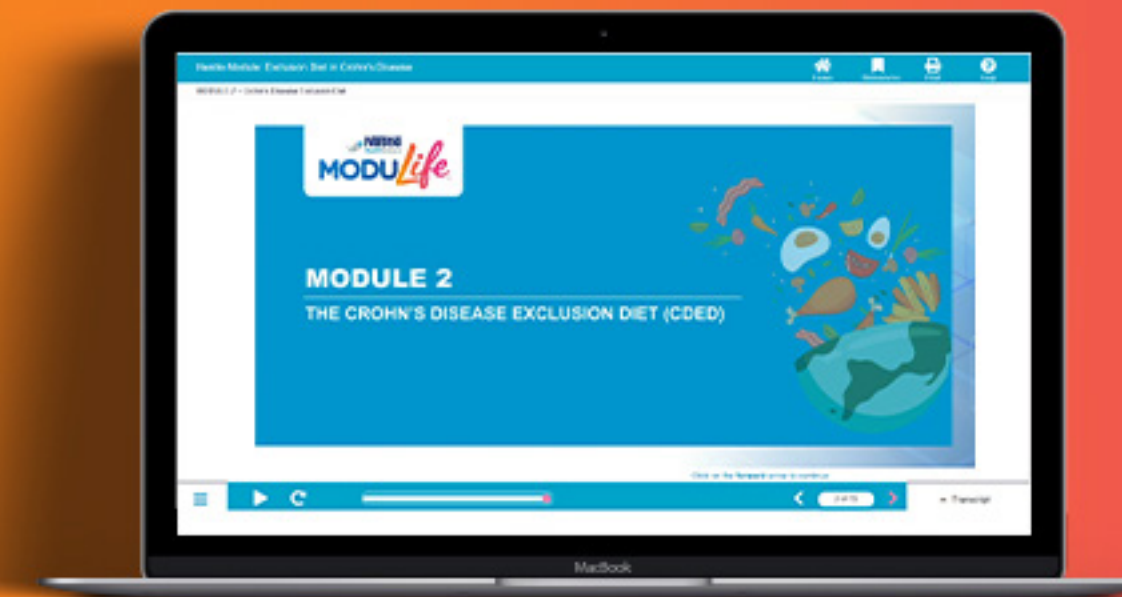
† TE = Total Energy



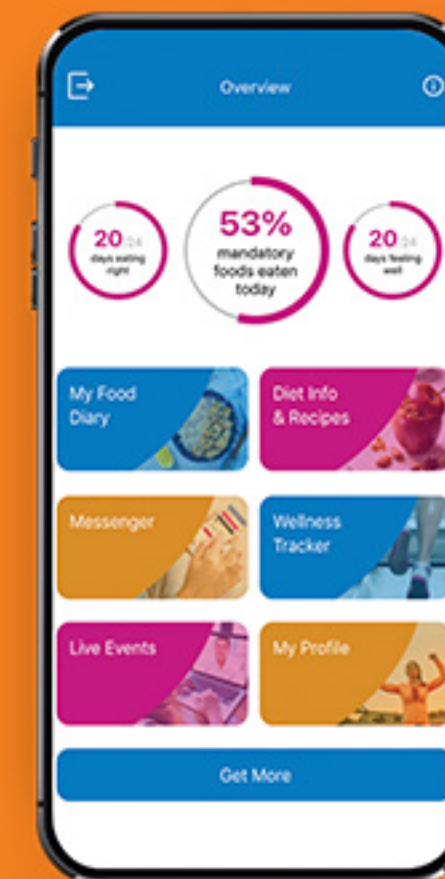
ModuLife™ is designed to support you and your patients throughout the CDED + PEN journey.



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



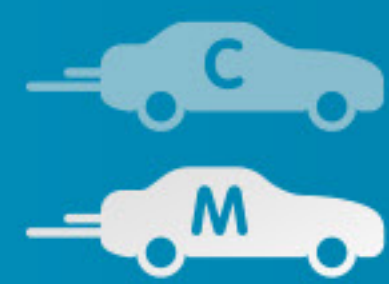
FOR HEALTHCARE PROFESSIONALS ONLY

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MODULEN® IBD, PROVEN EFFICACY AS EXCLUSIVE ENTERAL NUTRITION

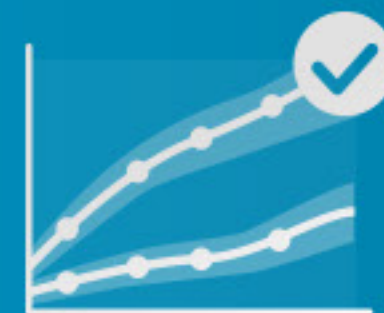
- Modulen® IBD has extensive clinical evidence as first-line therapy in paediatric CD¹⁻¹⁹



Induces remission as effectively and as rapidly as corticosteroids³



Superior mucosal healing vs corticosteroids³



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

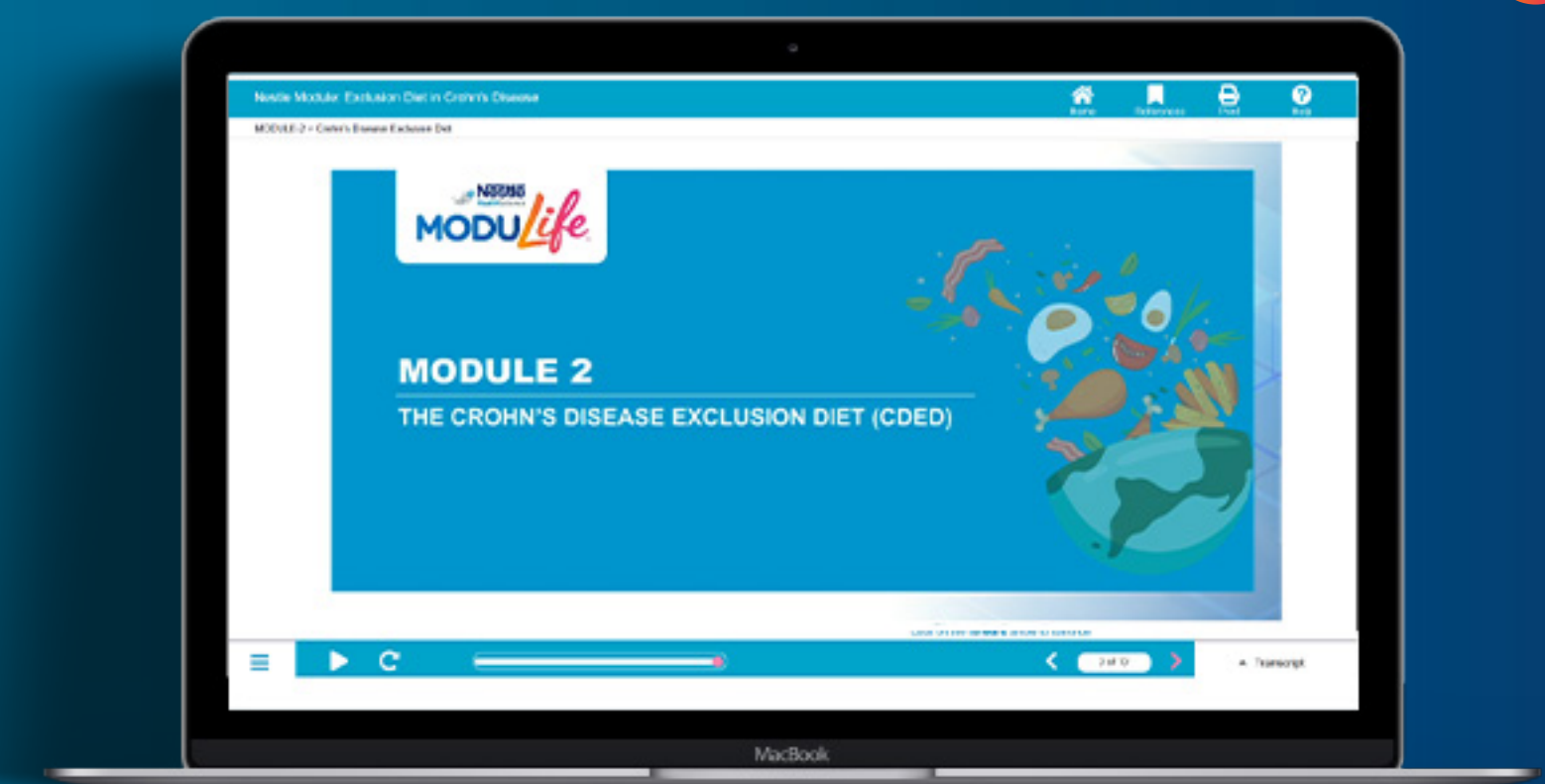


EXPERT TRAINING

- 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

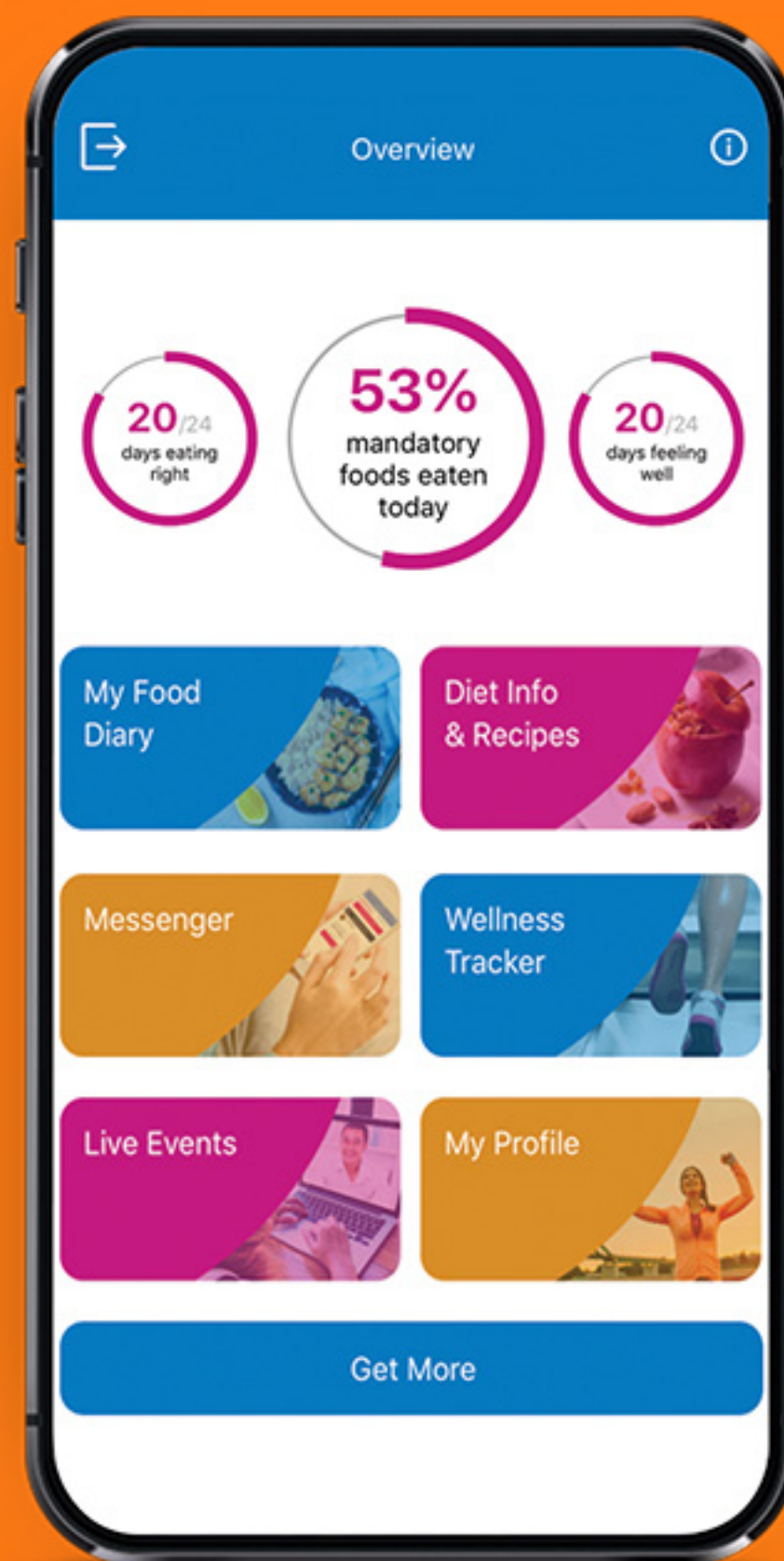


www.modulifexpert.com



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