The MOSS NUTRITION REPORT

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→ Product Review <</p>

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ELEMENTAL SELECTTM UPDATE:

REVISED DOSING **RECOMMENDATIONS**

It has been approximately six months since we first started providing **Elemental Select**[™] to you. If you are not familiar with the product, it is unique from all of our other powdered products in that it is a herb-free product designed to provide a complete complement of macro- and micronutrients for those patients who, due mainly to significant GI dysfunction, are having difficulty tolerating many, if not most foods, including those that are considered to be "healthy" by most standards. When we first started examining published research on products of this type approximately five years ago, we found papers that indicated that products of this type could be used successfully to improve gut function and food tolerance either with no food at all (Exclusive enteral nutrition - EEN) or in combination with 1-2 high quality meals per day (Partial enteral nutrition – PEN).

However, after six months of "in the trenches" feedback from many of you plus additional published research on EEN vs PEN, two key points became clear:

- EEN using **Elemental Select**[™] for periods of more than three days was challenging from a patient compliance standpoint due to cravings for solid food, boredom with the protocol, and the cost of prolonged use of **Elemental Select**[™] as an exclusive nutrition source.
- PEN using **Elemental Select**[™], assuming it includes a high quality, patient specific wholefoods diet, can be just as effective in terms of optimizing GI function and improving food

tolerance. Furthermore, with this scenario the patient monetary outlay for the product will be much less and compliance will be better due to a reduction in program boredom and food cravings.

With the above in mind, we are now revising our **Elemental Select**[™] usage recommendations to three options, each of which revolve around the concept of PEN.

Option #1 – The PEN Protocol

A common PEN protocol for people with ongoing gut issues is to take two scoops of **Elemental Select**[™] in place of one or two meals per day. (Two scoops of **Elemental Select**™ provide 300 calories; adjust the number of scoops to meet individual patient needs).

Option #2 - The Weekly Reset

Another approach is the "weekly reset" where the patient consumes a full elemental diet for one day per week. This full elemental diet will consist of ten scoops of **Elemental Select**TM which will provide 1500 kilocalories. For the other six days the PEN protocol outlined in option #1 will be followed.

Option #3 – The Moss Nutrition 3-Day Gut Reset

Patients with chronic gut imbalances may benefit from intensive use of a full elemental diet for three days, as outlined in option #2. This will be followed by a PEN diet while gut healing progresses. One 30-serving container of **Elemental Select**[™] is sufficient to complete a 3-Day Gut Reset at ten scoops/1500 kilocalories daily. The 3-Day Gut Reset may be followed by a

PEN diet, incorporating 2-4 scoops of **Elemental Select**TM per day, until desired results are achieved.

DOES PEN PROVIDE THE SAME HIGH QUALITY CLINICAL RESULTS FOR GI DYSFUNCTION COMPARED TO EEN?

Of course, a key question that needs to be addressed concerning protocols that revolve around PEN is whether they are as effective clinically as EEN protocols. When I first started reporting to you in this forum early in 2023 the results of studies on the use of products similar to **Elemental Select**[™], I noted that the research was clear about the efficacy of EEN. Is PEN, a much more practical and cost-effective approach, equal to EEN in terms of clinical efficacy? As you will see, it is, when combined with a high-quality diet as indicated in the study "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" by Sigall-Boneh et al (Sigall-Boneh R et al. Inflamm Bowel Dis, Vol. 20, No. 8, pp. 1353-1360, August 2014).

The first quote I would like to feature from this paper discusses the efficacy of EEN:

"Exclusive enteral nutrition (EEN) is a well-documented method of treatment. It involves placing children on a strict diet composed only of a single polymeric formula, as the sole source of nutrition over 6 to 8 weeks. Use of this treatment method, early in the disease, results in clinical remission of 50% to 80% of children by week 8 with no additional pharmacological agent."

However, as you might expect, when the same formula is used in a PEN format where the food sources are purely at the patient's discretion (free diet) the results are far from optimal:

"Previous studies and clinical experience have shown that partial enteral nutrition (PEN) with 50% of calories from a formula with free diet is ineffective in inducing complete remission or reducing acute phase reactants, suggesting that the effect of EEN appears to depend, at least in part, on exclusion of free diet."

Unfortunately, there is a dark underside to the fact EEN is only effective without the patient returning to his or her usual diet. Eventually, the patient will need to eat solid food again. For this reason, as you might expect, long term results with EEN have been disappointing, according to Sigall-Boneh et al:

"EEN is very effective for induction of remission in mild-to-moderate recent onset pediatric Crohn's disease. However, reported remission rates in pediatric studies have varied from 40% to 80%."

Therefore, from our standpoint, it is common sense that the most efficacious approach from a long-term standpoint will be the introduction of a high-quality diet at the same time gut repair is being promoted by the polymeric formula.

To determine the efficacy of such an approach the authors performed the following:

"Children and young adults with active disease defined as a pediatric Crohn's disease activity index >7.5 or Harvey-Bradshaw index ≥4 received a 6-week structured Crohn's disease exclusion diet that allowed access to specific food and restricted exposure to all other foods, and up to 50% of dietary calories from a polymeric formula."

The composition of the study group was the following:

"Forty-seven patients meeting all inclusion and exclusion criteria (34 children, 13 adults; mean age 16.1 ± 5.6 yr; mean disease duration, 2.1 ± 3.4 yr; range, 6-32 yr) were available for analysis."

It is also interesting to note that some of the participants were being treated for the first time and others were being treated because of relapse or poor response to previous therapies:

"In 14 patients, this was the first treatment offered after diagnosis. In all others, the treatment was offered because of a relapse or lack of response to a previous therapy."

What were the results of the study? Sigall-Boneh et al point out:

"Remission was obtained in 70% of children and 69% of adults. Normalization of previously

elevated CRP occurred in 21 of 30 (70%) patients in remission."

It is also both interesting and encouraging to note that some of the patients did the diet alone without the polymeric formula. As you will see, the results with these patients were also impressive:

"...the diet seemed to be effective even in patients who did not take any supplemental formula (no PEN), as evidenced by the fact that 6/7 patients who just used the Crohn's disease exclusion diet without any formula entered full remission. This is significant because the Crohn's disease exclusion diet allows access to specific foods to improve palatability and allowed patients who would have otherwise refused to use nutritional therapy, an alternative to steroids and biologics for induction of remission in mild-to-moderate disease."

With the above in mind, we assume that dietary changes have been employed with potential **Elemental Select**TM candidates and that use of **Elemental Select**TM is being instituted after dietary interventions have failed to deliver desired results. If this is not the case, we do recommend dietary interventions before use of **Elemental Select**TM.

In concluding their paper, Sigall-Boneh et al make two important points. First, even though EEN is effective, compliance is always a challenging weak link:

"The biggest drawback is the difficulty in implementing an exclusive monotonous liquid diet for 6 to 8 weeks."

Even more important, though, is the probability that PEN with a high-quality diet is just as efficacious as EEN:

"Although we cannot compare head-to-head efficacy, the remission rate in our study (70%) is similar to the 75% remission rate using oral EEN therapy in a large French study."

With the above in mind, the authors conclude:

"...we believe that PEN with the Crohn's disease exclusion diet may be useful for patients with mild-to-moderate disease as an alternative to EEN."

SOME FINAL THOUGHTS

As I mentioned above, we excited and gratified about your very positive feedback about **Elemental Select**TM. However, your feedback also made it clear that our initial recommendations about the use of **Elemental Select**TM as an EEN product may not be practical for many patients from both cost and compliance standpoints.

Therefore, based on your feedback plus the excellent results for a PEN approach as highlighted by Sigall-Boneh et al, we have made the decision to provide different options for the use of **Elemental Select**[™], all of which involve a PEN format. This revision in dosing recommendations can be found in our revised technical bulletin for the product which can be found on the Moss Nutrition website here: https://www.mossnutrition.com/product/elemental-select-1.04-Kg-2.3-lbs-m148/

Finally, if you would like a more detailed description of the 3-day gut reset elemental diet protocol using **Elemental Select**[™], please go to our website to see an excellent article on the subject by Diana Allen, MS, CNS, the Product Development Manager for Moss Nutrition. "After the Feast: A 3-Day Gut Reset Restores Digestive Comfort"