

## **EQUAZEN<sup>®</sup> PRO**

is a medical food to support learning, concentration, and brain development in children and adolescents with ADHD who have been determined by medical evaluation to require nutritional management of polyunsaturated fatty acid deficiencies that cannot be achieved by modification of normal diet alone.

#### What is the difference between a medical food and a dietary supplement?

Dietary supplements are exactly that: products intended to enhance wellness by supplementing nutrients or certain ingredients in the diet. Such ingredients can include anything from vitamins and minerals to herbs, botanicals, probiotics, amino acids, enzymes, or targeted combinations of a number of these. Unlike medical foods, supplement formulas are designed to provide nutritional support for individuals in overall good health. And, although it's best practice to consult with your healthcare practitioner for recommendations, dietary supplements may be taken without professional medical guidance.

Medical foods, however, are specially formulated and intended for the dietary management of a disease or condition that has distinctive nutritional needs which cannot be met by the modification of normal diet alone. All ingredients or substances that are added to medical foods are Generally Recognized As Safe (GRAS)—that is, they have been adequately shown to be safe under the conditions of their intended use. Because patients who use these solutions have health conditions that require medical management, medical foods are to be used under the ongoing supervision of a healthcare practitioner to ensure that the right amount is administered and adjusted as needed.

# Because EQUAZEN® PRO is a medical food, can I receive reimbursement from my medical insurance provider? Do I need a prescription from my physician to purchase EQUAZEN® PRO?

Reimbursement is determined by the details of your medical insurance plan. Plans, benefits, and reimbursements vary among different insurance companies, so be sure to contact your provider to learn more about their policies concerning medical foods. Furthermore, while a prescription is not required for you to purchase a medical food, your insurance provider may expect your physician to supply specific information for reimbursement qualifications to be met.

#### How many EQUAZEN® PRO softgels should my child take per day?

For children 5 years of age and above: 2 softgels daily with food or as directed by a healthcare practitioner. This serving size is based on the positive outcomes of multiple clinical studies, all of which were conducted specifically with Equazen Pro and in children and adolescents with ADHD.

### How long will it take before I can see, and my child can experience, the positive benefits of taking EQUAZEN® PRO?

Equazen Pro provides a balanced intake of omega-3 and omega-6 polyunsaturated fatty acids (PUFAs). However, because these nutrients are rapidly utilized by the body, they must be constantly replenished in order for optimal benefits to be experienced. Approximately twelve weeks is the average amount of time needed for the body to build up stores of omega fatty acids and, thus, for positive results to become recognizable. But, this duration may vary due to individual differences, such as diet, lifestyle, and overall health.

### What is the source of your fish oil, and what types of fish are used to produce the fish oil ingredient in EQUAZEN® PRO?

The fish oil in Equazen Pro has been harvested by companies that are certified by an international, independent authority for their compliance with the sustainable fisheries guidelines of the United Nations' Food and Agriculture Organization (FAO). More specifically, our fish oil is sourced from suppliers certified by Friend of the Sea® (FOS®), an internationally recognized, non-profit, non-governmental organization whose mission is to conserve the global marine habitat. FOS® operates leading certification projects that verify the sustainability of fisheries, as well as fish and omega-3 fish oil products. These certifications guarantee that high-quality standards are met—standards that promote energy efficiency and social accountability, including no overfishing, no bycatch of endangered species, and no harvesting of illegal, unreported, or unregulated (IUU) fish.

This fish oil is derived from cold-water fish (anchovies, sardines, and tuna) found in the Pacific, Atlantic, and Indian Oceans. These fish are harvested at very specific times of the year—more precisely, during those periods when they consume large quantities of plankton, which increases the amount of omega-3 fatty acids they contain.

#### How can I be assured of the purity of the fish oil used in EQUAZEN® PRO?

At SFI® Health, we make it our priority to guarantee the safety and sustainability of our products. Rest assured that there is no reason to be concerned about the purity of Equazen Pro.

In fact, every step in the production of Equazen Pro—from fishing to final product—has been developed to ensure the purity of its ingredients. The oil used in this formula is ethically sourced and derived from young, cold-water fish rich in omega-3s. The fish oil is then processed using PureMax® technology, which selectively concentrates the beneficial fatty acids—EPA and DHA—while also removing contaminants such as dioxins and mercury. The result? Some of the purest, safest, and most powerful omega-3 fatty acids. What's more, PureMax® technology also controls and minimizes the presence of the oxidative impurities that are often responsible for the unpleasant odor and aftertaste associated with omega-3 fish oil products.

In its entirety, the PureMax<sup>®</sup> process removes or minimizes a wide variety of contaminants, including:

- + Oxidative impurities
- + Dioxins and furans
- + Polychlorinated biphenyls (PCBs)
- + Dioxin-like PCBs
- + Heavy metals (arsenic, cadmium, lead, and mercury)
- + Polyaromatic hydrocarbons (PAHs)



The fish oil used in Equazen Pro is also manufactured under the stringent quality system of a UK-based production plant. Operating in accordance with European Pharmacopoeia reference standards, this facility ensures that every single batch produced is tested against strict Good Manufacturing Practices (GMP) specification parameters to provide 100% confidence to our customers.

#### Is the fish oil used in EQUAZEN® PRO tested for mercury levels?

Yes! But, that's not all we test for. From the initial fish oil concentrate to the packaged product, Equazen Pro undergoes several rounds of rigorous testing to identify any potential environmental contaminants. These tests help to detect the presence of heavy metals—lead, mercury, cadmium, and arsenic—dioxins, furans, and dioxin-like PCBs, polycyclic aromatic hydrocarbons (PAHs), and an extensive list of over 65 herbicides and pesticides. In addition to in-house testing, we also send samples of the finished product to an independent, third-party testing facility to confirm our results. We are in full compliance with stringent legislative regulations—those dictated by the U.S., the E.U., and WHO—related to quality assurance, food safety, and contamination, which together determine the production and use of fish oils for human consumption.

#### Can my child stop taking EQUAZEN® PRO for a while?

Unless otherwise directed by a healthcare practitioner, we recommend continual supplementation with Equazen Pro to achieve optimal results. The reasoning behind this recommendation is directly tied to the ways in which the body uses and stores fatty acids. Different fatty acids remain in the body for different lengths of time; for example, EPA can decrease to half of its maximum level within 24 hours. The beneficial omega fatty acids found in Equazen Pro, including EPA, are not stored for long periods of time, and their levels of concentration fall rapidly if they are not continuously supplemented.

### How do you ensure that the gelatin used in the EQUAZEN® PRO softgels does not contain bovine spongiform encephalopathy (BSE)? Is the gelatin halal and kosher certified?

The gelatin used in our softgels is made from animal tissue not considered to be "specified risk materials" regarding BSE. Additionally, several independent studies have found that the heat and pressure used to process the gelatin result in a product with no detectable potential for infection. We take TSE (transmissible spongiform encephalopathy) compliance extremely seriously; in fact, we meet stringent TSE compliance standards via certification. A TSE compliance certificate is a type of Certificate of Suitability (CEP) that confirms a material's adherence to the standard measures used to minimize the risk of TSE contamination. These CEPs are recognized by members of the European Pharmacopoeia as well as institutions in other countries, such as the FDA in the United States. To complement these strict manufacturing regulations, the ingredients gelatin and glycerol used in Equazen Pro softgels are also halal and kosher certified.

#### Are there any undesirable effects that might result from taking EQUAZEN® PRO?

Omega-3 fatty acids have been an important part of the human diet for millennia. As a result, the established safety profile for

polyunsaturated fatty acids (PUFAs)—including EPA and DHA—is considered high, and most of their associated undesirable effects are related to bruising and, for some, a slight increase in nosebleeds. The FDA has ruled that the consumption of up to 3 grams of marine omega-3 fatty acids per day is considered "GRAS" (Generally Recognized As Safe). Rest assured that the amount of omega fatty acids found in Equazen Pro is well within this safe range. In fact, clinical studies with Equazen Pro have demonstrated the occurrence of very few undesirable effects, the majority of which were mild gastrointestinal (GI) disturbances.

### Can my child take EQUAZEN<sup>®</sup> PRO with other medications or supplements? Would there be any risk of interactions?

Equazen Pro has been clinically studied in human trials to provide safe and effective nutritional support in combination with traditional ADHD therapy.<sup>1</sup>

Fish oils and other products containing omega-3 fatty acids may, albeit rarely, increase the risk of bleeding when combined with other medications that also increase the risk of bleeding, such as ibuprofen and aspirin. Always consult with a physician before taking fish oil products concomitantly with anticoagulant or antiplatelet medications.

#### Why is EQUAZEN® PRO priced at a premium in comparison to other fish oil products?

SFI® Health is dedicated to supplying our consumers with products of the highest quality—premium, scientifically tested formulations that represent our passion for proven healthcare solutions.

While there is reputable research demonstrating the many benefits of omega-3s, omega-6s, and fish oils generally, Equazen Pro's unique formula is supported by over 15 years of ongoing research. To date, we have performed 19 human clinical studies, 8 of which were conducted solely in individuals with ADHD, with demonstrated beneficial outcomes in learning, concentration, and brain development.<sup>†</sup>

Together with this strong history of clinical efficacy, Equazen Pro also contains premium ingredients. The fish oil used in this product is ethically sourced and produced with meticulous care under stringent quality standards; it is provided in its highly bioavailable form, making it readily usable by the body.

### The world's oceans are in serious danger of fish depletion. What is SFI<sup>®</sup> Health doing about this?

Sustainability is a top priority in the production process of Equazen Pro. The fisheries that serve in our supply chain are certified by Friend of the Sea®, an organization committed to responsible sourcing and traceability. This network provides every assurance that the fisheries we source are operating ethically and conscientiously; an independent third-party monitoring on behalf of the Friend of the Sea® governing body closely supervises quota catches, fish size, product testing, and loading for export.

#### Isn't omega-6 a "bad fat"?

Omega-6 is far from a "bad fat." In fact, it is an essential fatty acid that must be included in the diet. The ideal dietary ratio of omega-6s to omega-3s is around 1:1 to 4:1, but most Western diets result in ratios of 16:1 to 30:1—a disparity to which human beings are not genetically adapted. Scientists suspect that a distorted ratio of these polyunsaturated fatty acids may be one of the most damaging aspects of the Western diet. And, even further, this dietary imbalance may contribute to inflammation imbalance in the body, which can be detrimental to optimum health, including healthy cognitive function. The higher concentrations of omega-3s versus omega-6s in Equazen Pro is specially designed to help correct the fatty acid ratio.

Additionally, the evening primrose oil in Equazen Pro contains omega-6 γ-linolenic acid (GLA), which plays a crucial role in inflammation modulation and is vital to healthy omega-6/omega-3 balance. When supplemented in the diet, GLA is rapidly converted to dihomo-γ-linolenic acid (DGLA). DGLA is found to modulate the formation of inflammatory molecules, enhance the beneficial actions of omega-3 fatty acids, and boost the levels of EPA and DHA in the brain.

#### Can I give EQUAZEN® PRO to my baby?

Due to a potential choking hazard, Equazen Pro is not recommended for children under 5 years old. It is suitable for children 5 years of age and older.

#### Can I take EQUAZEN® PRO while pregnant?

Equazen Pro is not intended to be consumed by women who are pregnant or nursing.

#### I am allergic to fish protein/I have a fish allergy. Can I still take EQUAZEN® PRO?

Equazen Pro contains refined fish oil that undergoes several processing steps—including water washing, freezing, filtration, and

steaming—in order to remove any protein traces. It is very unlikely that any fish proteins remain in the oil. However, because trace levels of fish protein may still be present, and because we cannot completely exclude the risk, we do not recommend this product if you have a fish allergy.

### My child finds it difficult to take EQUAZEN® PRO softgels. Can you please offer some serving suggestions?

Some children may find it difficult to take softgels, especially when fish-derived products are involved. If your child is struggling to take Equazen Pro, because:

- + **They are new to taking softgels:** Engage your child in a conversation about the reasons for taking the softgels. Children should understand the purpose of the product and how it can benefit them.
- + They find it difficult to swallow:
  - + Demonstrate the process! Have them watch you swallow a softgel product yourself. First, visually display the softgel on your tongue, then drink liquid, and, finally, show them that the softgel is all gone.
  - + Have them put water in their mouth first and then the softgel. This prevents the softgel from sticking to the tongue, which can cause a sensory aversion, and it makes the act of swallowing the softgel seem less threatening because it feels similar to swallowing water.
  - + Encourage them to try to swallow the softgel with a spoonful of apple sauce or other fruit puree. The thicker texture of purees can help to engage their swallowing reflex.
  - + If swallowing the product still proves difficult, you can place the softgel in a cup of water for 15 minutes to soften it. Then carefully cut open the end and pour out the oil. This oil can be taken orally or added to foods like soup, mashed potatoes, apple sauce, and yogurt. Keep in mind that while adding Equazen Pro into food does not result in diminished effects, cooking with the oil should be avoided, as it damages the delicate structure of the fatty acids and hinders their efficacy.
- + They experience indigestion or "fishy burps": Although Equazen Pro uses a specific enteric coating technology that reduces the possibility of fishy taste or reflux, many parents report that they prefer their child to take the softgel along with with the evening meal so that the oil can be absorbed within the body as the child sleeps.

#### Has EQUAZEN® PRO been tested in human clinical trials?

Yes! Equazen Pro is supported by over 15 years of clinical research and has been extensively studied in 8 randomized, placebocontrolled human trials in children with ADHD. To date, more than 19 clinical trials have been conducted with the product. Further SFI® Health-sponsored trials are ongoing.

#### Which is more important, EPA or DHA?

It is impossible to say which of these two omega-3 fatty acids— eicosapentaenoic acid (EPA) or docosahexaenoic acid (DHA)—is more important than the other. Both are conditionally essential nutrients that enhance quality of life, and a combination of the two contributes to a wide variety of important functions throughout the body. At sufficient levels, EPA and DHA support the structure of cell membranes and influence many aspects of tissue physiology, including cell signaling, gene expression, and inflammation modulation. DHA is also a proven essential nutrient in fetal and infant brain development, while EPA plays a central role in the communication between cells in the brain, which is why it seems to be more influential on behavior and mood. Additionally, both DHA and EPA possess neuroprotective properties and support brain repair mechanisms.

#### What makes EQUAZEN® PRO different from other fish oil products?

More often than not, traditional fish oil products only contain omega-3 fatty acids. Equazen Pro, however, supplies a scientifically developed combination of both omega-3 fatty acids—EPA and DHA—and an omega-6 fatty acid—GLA—in a unique ratio of long-chain polyunsaturated fatty acids which may not be achievable through the modification of normal diet alone. This carefully balanced formula is backed by over 15 years of strong scientific research, which offers peace of mind to both practitioners and parents for its efficacy and use as a medical food to support learning, concentration, and brain development in children and adolescents with ADHD.<sup>†</sup>

1 Barragán E, Breuer D, Döpfner M. Efficacy and Safety of Omega-3/6 Fatty Acids, Methylphenidate, and a Combined Treatment in Children With ADHD. *J Atten Disord*. 2017 Mar;21(5):433-441.

†EQUAZEN\* PRO is a medical food designed to support learning, concentration, and brain development in children/ adolescents with ADHD who have been determined by medical evaluation to require the nutritional management of polyunsaturated fatty acid deficiencies that cannot be achieved by modification of normal diet alone.

NOTICE: EQUAZEN<sup>®</sup> PRO IS A MEDICAL FOOD TO BE USED UNDER THE SUPERVISION OF A PHYSICIAN OR OTHER LICENSED HEALTHCARE PRACTITIONER. IT IS NOT A REPLACEMENT FOR ANY MEDICATION.

