Vayarin® is a prescription medical food that addresses the lipid imbalances associated with ADHD and is for use under physician supervision.
Vayarin
Medical food for the dietary management of ADHD

GET YOUR 3RD MONTH FREE**

PROMO CODE: VAYARIN90DAYS

VAYA Direct is a service available to patients with a prescription for VAYA Pharma products, including Vayarin®. This convenient service allows you to receive Vayarin® affordably and efficiently – shipped directly to your door.

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VAYA-DIRECT.com

**offer available on first prescriptions only; shipping charges may apply.

Vayarin is a prescription medical food that addresses the lipid imbalances associated with ADHD and is for use under physician supervision.

Questions? Learn more at vayarin.com or contact us at 410-297-0020 or contact@vayapharma.com
VAYARIN® IS CLINICALLY SHOWN TO REDUCE ADHD BEHAVIORS, ESPECIALLY IN CHILDREN WITH MORE PRONOUNCED EMOTIONAL DYSREGULATION

Double-Blinded Placebo Control Phase (Week 0-15)
Vayarin® 4 capsules per day

Results with the subgroup: Children were included in this subgroup if they had an abnormal baseline score (<62) in at least two out of the following CRS T subscales: Oppositional, Hyperactivity, ADHD-index, or Global: Emotionally liability. #p ≤ 0.15 *p < 0.05 Based on analysis of covariance controlled for gender and age.


VAYARIN® IS CLINICALLY SHOWN TO IMPROVE QUALITY OF LIFE

Based on Student’s t-test. Similar results were observed within a subset of hyperactive-impulsive children.

THE VAYARIN® DIFFERENCE

Vayarin® is a specially designed lipid composition that targets the brain.

Its structure combines Phosphatidylserine (PS) and Omega-3, creating PS-Omega-3, a composition that is designed to travel efficiently to the brain and provide vital nutrients needed to manage the lipid deficiency associated with ADHD. This unique structure is what differentiates Vayarin® from other lipid based products.

WHY IT WORKS

• Vayarin® gets lipid nutrients to the brain
• Vayarin’s unique composition is specifically designed to increase the bioavailability of lipid nutrients across the Blood Brain Barrier (BBB)
• Vayarin’s special formulation addresses lipid imbalances that cannot be addressed by modification of the diet alone

*Long-chain polyunsaturated fatty acids

Vayarin® Composition
Phosphatidylserine-Omega-3

Polar Head
Serine
Phosphate
Glycerol
Omega-3 LC-PUFA*

Fish Oil Triglyceride

PS-OMEGA-3 RESULTED IN HIGHER BIOAVAILABILITY TO THE BRAIN

A significant increase of 42% in DHA bioavailability in the brain versus other forms*


*Data based on animal model

**p < 0.05 compared to control, based on one-way ANOVA
Lipirinen® is a proprietary composition containing phosphatidylserine (PS) conjugated to omega-3 fatty acids enriched with Eicosapentaenoic acid (EPA).

Lipids IMbalances in ADHD

There is a growing body of scientific evidence demonstrating that low levels of certain lipids are associated with Attention Deficit Hyperactivity Disorder (ADHD). While ADHD is a complex disorder, the etiology of which is multi-factors, ADHD has been shown to be associated with metabolic disturbances such as lipid and glucose metabolism [1, 2]. The abnormalities in lipid metabolism that may occur in ADHD are associated with increased oxidative stress, higher rates of lipid degradation and decreased synthesis of phospholipids containing omega-3 fatty acids. Reduced levels of certain lipids are associated with higher rates of oxidative stress, increased rates of synaptic loss, impaired cell communication, and cell growth regulation [4]. Thus, reduced levels of PS-Omega-3 play an important role in the functioning of neuronal phospholipids pool [26].

Each Vayarin® capsule provides:

- 75 mg Lipirinen®
- 250 mg Lutein
- 25 mg Rosemary extract
- 25 mg Sunflower oil
- 50 mg Ascorbyl palmitate
- 25 mg Mixed tocopherols
- 10 mg D-gamma-tocopherol
- 10 mg D-delta-tocopherol

Vayarin® contains shellfish (krill) and should be used with caution in patients with known shellfish allergies. It is not recommended for use during pregnancy or lactation.

CLINICAL EXPERIENCE

Vayarin® was studied as a single-center randomized double-blind placebo-controlled study of 15 weeks followed by an open label extension (OLE) of an additional 15 weeks. In the double-blind phase two hundred ADHD children (aged 6-13 years) were randomly assigned to receive Vayarin® or placebo (four capsules a day). In order to evaluate the effect of a reduced dose, an OLE was conducted in 150 participants, assigned to consume two capsules a day. The effect of Vayarin® was assessed by rating scales and questionnaires, including the Conners’ parent (CRS-P) and teacher (CRS-T) rating scales and the child health questionnaire (CHQ) [37].

Figure 2. Effect of Vayarin® (n=46-50) versus placebo (n=23-25) on CRS-P and CRS-T scores following 15 weeks of administration during the double-blind phase, within the subgroup of participants with more pronounced emotional dysregulation. Values are presented as mean ± SE. P values are based on analysis of covariance controlled for gender, age, P<0.05, WP<0.2.

PHYSICIAN SUPERVISION

Vayarin® is a medical food product dispensed by prescription and must be used under physician supervision.

CONTRAINDICATIONS

Vayarin® is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vayarin® or any of its components.

PRECAUTIONS

- Safety and effectiveness of Vayarin® in pediatric patients or pregnant or lactating patients have not been established. Therefore, Vayarin® is not recommended for use during pregnancy or lactation.

- Vayarin® contains shellfish (krill) and should be used with caution in patients with known hypersensitivity to shellfish.
Study design
Double-blind study (4 capsules/day)
Open-label extension (2 capsules/day)

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Vayarin® (n=137)</th>
<th>Placebo (n=63)</th>
<th>Vayarin® (n=150)</th>
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<tbody>
<tr>
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Table 2. Adverse events reported during the course of the double-blind and open label phase.

*Judged by the physicians as related or probably related to the study treatment

DOSAGE AND ADMINISTRATION
Usual dose is two capsules daily or as directed by a physician.

INDICATION AND USAGE
Vayarin® and Lipirinen® are indications of Enzymotec Ltd.

WARNING
Store at up to 77oF (25oC). Protect from light and moisture.

Adverse events reported during the course of the open-label extension (table 5) of the physician rejection of the study treatment, or related events (3 and 5 adverse events, respectively). There were no significant differences between the study groups in either the incidence or number of adverse events recorded (P = 0.848 and P = 0.982, respectively).

Vayarin® and Lipirinen® are registered trademarks of Enzymotec Ltd.

REFERENCES