

Vayarin®

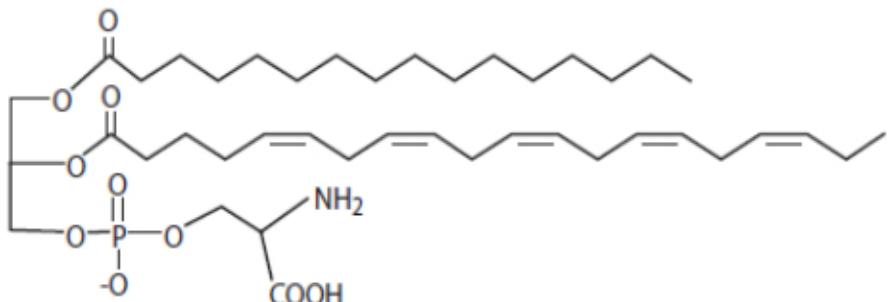
DESCRIPTION

Vayarin® is an orally administered prescription medical food for the clinical dietary management of certain lipid imbalances associated with ADHD in children.

Each capsule contains Lipirinen™ 167 mg, providing:

Phosphatidylserine (PS)	75 mg
Eicosapentaenoic acid (EPA)	21.5 mg
Docosahexaenoic acid (DHA)	8.5 mg

CHEMICAL STRUCTURE*



* Schematic structure of one of the most abundant molecules present in Vayarin®.

INGREDIENTS

Phosphatidylserine, Hypromellose, Silicon Dioxide, Rosemary Extract (preservative), Mixed Tocopherols (E306-E309), Ascorbyl Palmitate (E304), Titanium Dioxide (color), Caramel (color).

Vayarin® capsules contain shellfish (krill).

May contain soy and fish.

Vayarin® capsules do not contain sugar, lactose, yeast or gluten.

PHARMACOLOGY

Vayarin® is composed of Lipirinen™, a proprietary composition containing phosphatidylserine-omega-3, EPA enriched.

• Mechanism of action

Omega-3 long-chain polyunsaturated fatty acids (LC-PUFA) have an important role in brain and central nervous system development and functioning [1-4]. Decreased omega-3 fatty acids levels, mainly DHA and EPA, are associated with the occurrence of psychiatric, neurodegenerative, and other neurodevelopmental disorders such as dyspraxia, dyslexia, autism [3], peroxisomal disorders [5], Alzheimer's disease [6], and ADHD [3]. Administration of phosphatidylserine (PS) enriched with omega-3 fatty acids was found to significantly increase DHA level in rat brains [7].

While the exact mechanism by which Vayarin® exerts its effects is not fully understood, PS present in the mammalian nervous system, which is characterized by its substantial levels of omega-3 fatty acids, has been implicated in numerous membrane related functions, such as maintaining the integrity of cell membranes, cell excitability, cell-to-cell recognition and communication [8]. PS has been found to regulate key proteins in neuronal membranes, including sodium/calcium ATPase [9] and protein kinase C [10] which undertake crucial functions in diverse signal transduction pathways. Similarly, PS interacts with Raf-1 protein kinase to promote a cascade of reactions that are believed to be involved in cell survival [11]. Additionally, PS has been found to influence neurotransmitter activity, such as the release of acetylcholine, dopamine and noradrenaline [12, 13] and to increase brain glucose levels.

• Absorption and Metabolism

Following dietary ingestion of phospholipids, pancreatic digestive enzymes cleave specific fatty acids, leading to the formation of lysophospholipids that are absorbed by the mucosal cells of the intestine and could be reacylated into phospholipids [14]. The fatty acids released can be further used for triglyceride synthesis. Because of the high activity of decarboxylases in the mucosal cells, the majority of the PS is converted into other phospholipids, primarily to phosphatidylethanolamine [15]. The reacylated PS, phosphatidylethanolamine and other phospholipids enter the lymph and circulation, and are redistributed.

• Drug interactions

PS can potentially interact with some anticholinergic and cholinergic medications. It is recommended to consult with a physician about Vayarin® interactions that may apply to specific medical conditions.

CLINICAL EXPERIENCE [17, 18]

Double-blind study

Method: A 15-week, double-blind, placebo-controlled clinical trial was conducted with 200 ADHD children randomized to receive either Vayarin® or placebo (4 capsules/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).

Results: 162 participants completed the study, of whom 147 were included in the efficacy analysis. Significant reduction in ADHD scores was detected in the CRS-P assessment. In addition, a significant beneficial effect was observed in the quality of life questionnaire (CHQ). Subgroup analysis of children with a hyperactive/impulsive behavior, as well as mood and behavior-dysregulation, revealed a more pronounced reduction in ADHD scores.

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.

PRECAUTION

Safety and effectiveness of Vayarin® in pregnant or lactating patients have not been established. Therefore, Vayarin® is not recommended for these populations. Vayarin® should be used with caution in patients with known hypersensitivity to shellfish.

DRUG ABUSE

Vayarin® does not have any known drug abuse or withdrawal effects.

ADVERSE EVENTS

According to both the double-blind study and open-label extension, Vayarin® was well tolerated. Children maintained good health throughout both study phases (30 weeks) and no major adverse events were noted by the study physicians. In the double-blind study, 13 adverse events (in 12 participants) were classified as possibly or probably treatment-related in the Vayarin® group. These included 6 cases of gastrointestinal discomfort, one case each of atopic dermatitis, hyperactivity, tics, nausea, elevated serum glutamic oxaloacetic transaminase (SGOT) and two cases of tantrum episodes. In the placebo group, 5 adverse events (in 5 participants) were classified as possibly or probably treatment related. These included 4 cases of gastrointestinal discomfort and one case of headache. In the open-label extension, 7 adverse events, classified by the study physicians as possibly or probably treatment-related, were recorded. These included 4 cases of gastrointestinal discomfort, one case each of headache, insomnia and high triglyceride level.

DOSAGE AND ADMINISTRATION

Usual dose is 2 capsules daily or as directed by a physician.

HOW SUPPLIED

Available as hard shell capsules. Commercial product is supplied in bottles of 60 capsules.

Commercial Product (60 capsules)	75959-233-60*	Use under medical/physician supervision.
Sample Product (4 capsules)	75959-233-04*	Professional Samples -Not for sale.

* VAYA Pharma™ does not represent these product codes to be actual National Drug Codes (NDCs). NDC format codes are product codes adjusted according to standard industry practice to meet the formatting requirements of pharmacy and health insurance computer systems.

STORAGE

Dispense and keep in original bottle.

Store at up to 77°F (25°C). Protect from light and moisture.

WARNING

Keep this product out of the reach of children.

Vayarin® is composed of Lipirinen™, a proprietary composition containing phosphatidylserine-omega-3, EPA enriched.

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Capsules
Vayarin®



Vayarin®
Capsules