

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

GREENVINE PHARMACEUTICAL LIMITED

**Summary of Product
Characteristics**

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

Summary of Product Characteristics

1-NAME OF THE MEDICINAL PRODUCT

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN

1.1 Strength

Each 10ml contains

Omega3 (ala) 170mg

Omega 3 (epa) 100mg

Omega 3 (dha) 30mg

Phosphatidylcholine 50mg

Inositol 25mg

1.2 Pharmaceutical form

Oral solution ¹

For the full list of excipients, see section 6.1

2- QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative declaration

Active substance: Omega-3 rich fish oil

Excipients: Natural tocopherols, Rosemary extract, Ascorbyl palmitate, Sunflower oil and Tutti Frutti

2.2 Quantitative declaration

Name	Quantity per 100 ml solution	Composition per dose unit of 5 ml	Function
Marine Fish Oil	93 g	4.65 g	Principal ingredient

¹ “Syrup” used in the name of the product being a more common name for the patients/users

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

Name	Quantity per 100 ml solution	Composition per dose unit of 5 ml	Function
DHA	Min. 18 %	0.84 g	Active components
EPA	Min.11 %	0.51 g	
Total omega-3	Min.35%	1.62 g	
Anti-oxidant mixture of: - Natural tocopherols (E306) - Rosemary extract, - Ascorbyl palmitate (E304) - Sunflower oil	0.15 g (0.15 %)	7.5 mg	Anti-oxidant and odour adjustment
Tutti Frutti	1 g (1%)	50 mg	Flavour adjustment

3- PHARMACEUTICAL FORM

Oral solution

Light yellow oil with minimal taste and odour of fish

4- CLINICAL PARTICULARS

4.1 Therapeutic indications

A daily intake of 5 ml of Greenvine kids omega 3 Syrup helps to ensure the intake of Omega-3 fatty acids.

Greenvine kids omega 3 Syrup for children contains high levels of DHA and may help maintain levels of concentration and healthy development of children.

4.2 Posology and mode of administration

The recommended dose is 5 ml per day.

For oral use only.

4.3 Contraindications

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

The concomitant use of Greenvine kids omega 3 with aspirin and with anti-coagulants such as warfarin is contra-indicated, because omega-3 fatty acids can influence the function of the blood platelets.

4.4 Special warning and precautions for use

- People with fish allergies might be allergic to omega-3-acid ethyl esters, since it is made from fish oil. Although omega-3-acid ethyl esters are purified using a five-step refinement process, some people might still react to this medicine. People having a fish allergy should check with their healthcare provider before taking omega-3-acid ethyl esters.
- Before prescribing omega-3-acid ethyl esters, the healthcare provider should make sure to have tried to lower the patient's triglycerides without medications. This includes making any necessary diet or exercise changes, decreasing weight and alcohol consumption, stopping any medications that cause high triglycerides, and adequately treating any medical conditions that cause high triglycerides (such as diabetes, hypothyroidism, liver disease, or kidney disease).
- Even when taking omega-3-acid ethyl esters, it is still very important to keep up with the diet and exercise changes that healthcare providers recommend. Omega-3-acid ethyl esters is not a substitute for a proper diet and exercise.
- Some studies suggest that omega-2-acid ethyl esters might increase the risk of atrial fibrillation or atrial flutter (two types of irregular heart rhythms) in people with a history of such problems. This medication is not approved for treating atrial fibrillation or atrial flutter.
- The healthcare provider should check the patient's cholesterol and triglyceride levels periodically while using omega-3-acid ethyl esters. This is necessary to make sure that omega-3-acid ethyl esters are working and to make sure that the medicine is not increasing the LDL cholesterol ("bad cholesterol"), which can sometimes happen with omega-3-acid ethyl esters.

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

4.5 Interactions with other medicinal products and other forms of interactions

- Even though they are "natural" products, omega-3 fatty acid supplements can potentially interact with several medicines.
- Combining an omega-3 supplement with anticoagulant or antiplatelet medication may increase the risk of bleeding, including dangerous internal bleeding. An omega-3 fatty acid supplement should not be taken concomitantly with anticoagulant or antiplatelet medication.
- Greenvine kids omega 3 could interact with Orlistat (Alli, Xenical): orlistat works by blocking the absorption of fat into the body. This action could block the absorption of omega-3 fatty acids into the body. To avoid this problem, orlistat and the omega-3 supplement should be taken at least two hours apart.

4.6 Pregnancy, lactation and fertility

4.6.1 Pregnancy

Omega-3 fatty acids have been found to be essential for both neurological and early visual development of the baby. However, the standard western diet is severely deficient in these critical nutrients. This omega-3 dietary deficiency is compounded by the fact that pregnant women become depleted in omega-3, when the foetus uses omega-3 for its nervous system development.

Omega-3 fatty acids have positive effects on the pregnancy itself. Increased intake of EPA and DHA has been shown to prevent pre-term labor and delivery, lower the risk of pre-eclampsia and may increase birth weight. Omega-3 deficiency also increases the mother's risk for depression. This may explain why postpartum mood disorders may become worse and begin earlier with subsequent pregnancies.

4.6.2 Lactation

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

Omega-3 are also used after birth to make breast milk. With each subsequent pregnancy, mothers are further depleted. Research has confirmed that adding EPA and DHA to the diet of pregnant women has a positive effect on visual and cognitive development of the baby. Studies have also shown that higher consumption of omega-3 may reduce the risk of allergies in infants.

4.6.3 Fertility

There are no available data on the influence of Omega3 on human fertility.

4.7 Effects on the ability to drive and use machines

Not applicable

4.8 Undesirable effects

A review was made of 395 human clinical articles for reports of adverse events associated with omega-3 fatty acid consumption. 247 articles were rejected because they did not provide adverse event information and two additional articles that were duplicate publications. Of the remaining 148 articles in the general and CVD populations, a variety of adverse events were reported in 71 studies, but 77 RCTs and non-randomized comparison studies reported no adverse events. One hundred and forty-two articles provided data on about 20,000 subjects, about one-half of whom were exposed to different forms and dosages of omega-3 fatty acid for durations ranging from 1 to 364 weeks. The majority of the studies evaluated a few dozen subjects for less than 6 months. The GISSI-Prevention trial, that had over 11,000 subjects and a follow up duration of 182 weeks, reported the largest number of adverse events. This trial contributed about one-third of the total number of gastrointestinal complaints (in both the omega-3 fatty acid arm and the control arm) from all the studies combined, and also contributed almost all the withdrawals due to adverse events (although the reasons for withdrawals were not given). This discordance suggests that most other studies did not adequately report adverse event data, especially concerning withdrawals.

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

None of the serious adverse events that were reported associated omega-3 fatty acid consumption with events such as death, life-threatening illness, or significant disability or handicap, although two studies reported that some important bleeding occurred with fish oil combined with aspirin or warfarin.

4.9 Overdose

An omega-3 overdose is likely to cause any of the usual omega-3 side effects, but perhaps more severely. In particular, stomach upset can be expected. In serious cases, an overdose could increase the risk of bleeding, including dangerous internal bleeding, such as gastrointestinal bleeding or bleeding in the brain.

Symptoms of such bleeding may include:

- easy bruising or bleeding,
- black, tarry stools; bright red blood in the stool; or vomiting of blood (signs of gastrointestinal bleeding),
- signs of a haemorrhagic stroke (bleeding in the brain), such as vision or speech changes, weakness or numbness in an arm or leg, or a severe headache.

Treatment for an Omega-3 Overdose

It is not known how to best treat an omega-3 fatty acid overdose. Therefore, treatment (if necessary) will involve supportive care, which consists of treating the symptoms that occur as a result of the overdose. For instance, if an overdose caused bleeding, then supportive treatment would include medications or procedures to stop the bleeding. It is important that the user seeks prompt medical attention in case he believes to have overdosed on omega-3 fatty acids.

5- PHARMACOLOGICAL PROPERTIES

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

5.1 Pharmacodynamic properties

- The 'essential' fatty acids were given their name when researchers found that they are essential to normal growth in young children and animals, though the modern definition of 'essential' is stricter. A small amount of n-3 in the diet (~1% of total calories) enabled normal growth, and increasing the amount had little to no additional effect on growth.
- Likewise, researchers found that n-6 fatty acids (such as γ -linolenic acid and arachidonic acid) play a similar role in normal growth. However, they also found that n-6 was "better" at supporting dermal integrity, renal function, and parturition. These preliminary findings led researchers to concentrate their studies on n-6, and it is only in recent decades that n-3 has become of interest.
- In 1964, it was discovered that enzymes found in sheep tissues convert n-6 arachidonic acid into the inflammatory agent called prostaglandin E₂, which both causes the sensation of pain and expedites healing and immune response in traumatized and infected tissues.
- By 1979, more of what are now known as eicosanoids were discovered: thromboxanes, prostacyclins, and the leukotrienes. The eicosanoids, which have important biological functions, typically have a short active lifetime in the body, starting with synthesis from fatty acids and ending with metabolism by enzymes. However, if the rate of synthesis exceeds the rate of metabolism, the excess eicosanoids may have deleterious effects.
- Researchers found that certain n-3 fatty acids are also converted into eicosanoids, but at a much slower rate. Eicosanoids made from n-3 fatty acids are often referred to as anti-inflammatory, but in fact they are just less inflammatory than those made from n-6 fats. If both n-3 and n-6 fatty acids are present, they will "compete" to be transformed, so the ratio of long-chain n-3:n-6 fatty acids directly affects the type of eicosanoids that are produced. This competition was recognized as important when it was found that thromboxane is a factor in the clumping of platelets, which can both cause death by thrombosis and prevent death by bleeding. Likewise, the leukotrienes were found to be important in immune/inflammatory-system response, and therefore relevant to arthritis, lupus, asthma, and recovery from infections. These discoveries led to greater interest in

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

finding ways to control the synthesis of n-6 eicosanoids. The simplest way would be by consuming more n-3 and fewer n-6 fatty acids.

They are required during the prenatal period for the formation of synapses and cell membranes. These processes are also essential in postnatal human development for injury response of the central nervous system and retinal stimulation.

Conversion efficiency of ALA to EPA and DHA

The short-chain n-3 fatty acids are converted to long-chain forms (EPA, DHA) with an efficiency below 5% in men, and at a greater percentage in women which may be due to the importance for meeting the demands of the fetus and neonate for DHA. These conversions occur competitively with n-6 fatty acids, which are essential closely related chemical analogues that are derived from linoleic acid. Both the n-3 α -linolenic acid and n-6 linoleic acid must be obtained from food. Synthesis of the longer n-3 fatty acids from linolenic acid within the body is competitively slowed by the n-6 analogues. Thus, accumulation of long-chain n-3 fatty acids in tissues is more effective when they are obtained directly from food or when competing amounts of n-6 analogs do not greatly exceed the amounts of n-3. The conversion of ALA to EPA and further to DHA in humans has been reported to be limited, but varies with individuals. Women have higher ALA conversion efficiency than men, it is presumed due to the lower rate of use of dietary ALA for beta-oxidation. This suggests that biological engineering of ALA conversion efficiency is possible.

The n-6 to n-3 ratio

Some clinical studies indicate that the ingested ratio of n-6 to n-3 (especially linoleic vs α -linolenic) fatty acids is important to maintaining cardiovascular health. However, two studies published in 2005 and 2007 found that while n-3 polyunsaturated fatty acids are extremely beneficial in preventing heart disease in humans, the levels of n-6 polyunsaturated fatty acids (and therefore the ratios) were insignificant. Both n-6 and n-3 fatty acids are essential; i.e., humans must consume them in the diets. N-6 and n-3

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

eighteen-carbon polyunsaturated fatty acids compete for the same metabolic enzymes, thus the n-6:n-3 ratio will significantly influence the ratio of the ensuing eicosanoids (hormones), (e.g., prostaglandins, leukotrienes, thromboxanes, etc.), and will alter the body's metabolic function. In general, grass-fed animals accumulate more n-3 than do grain-fed animals, which accumulate relatively more n-6. Metabolites of n-6 are more inflammatory (esp. arachidonic acid) than those of n-3. This necessitates that n-6 and n-3 be consumed in a balanced proportion; healthy ratios of n-6:n-3 range from 1:1 to 1:4 (an individual needs more n-3 than n-6).

5.2 Pharmacokinetic properties

Once absorbed, omega-3 is incorporated into the protective membrane of the cells, where it affects the metabolic activities within the cell.

5.3 Preclinical safety data

No data available

6- PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oily natural extract mixture Oxyblock[®] BA 150810 (contains Natural tocopherols, Rosemary extract, Ascorbyl palmitate, Sunflower oil),
Tutti Frutti flavour

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

6.4 Special precautions for storage

The product should be stored below 30 °C in its original packaging, protected from light and humidity. Do not freeze.

The container should be tightly closed after each use.

6.5 Nature and contents of container

Amber coloured Polyethylene terephthalate (PET) bottle which is tightly closed with a white polyethylene screw-cap.

Box with one bottle of 100 ml solution, a measuring device suitable for dosing 5 ml and a leaflet.

6.6 Special precautions for disposal and other handlings

Any unused product or waste must be disposed of in accordance with applicable regulations.

GREENVINE KIDS OMEGA-3 SYRUP FOR INFANT AND CHILDREN SMPC

7- MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

7.1 Marketing Authorisation Holder

GREENVINE PHARMACEUTICAL LIMITED

30 Adekitan Street, off palm Avenue, mushin, Lagos state

8. Manufacturer
Jehyson Healthcare Limited,
Jehyson Crescent,
Ewekoro, Ogun State.