# GREENVINE DHA WITH CHOLINE AND INOSITOL MALT FLAVOURED SMPC

**GREENVINE PHARMACEUTICAL LIMITED**

**Summary of Product Characteristics**

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## 1. Name of the medicinal product

GREENVINE DHA Emulsion

## 2. Qualitative and quantitative composition

Each 5ml contains
50mg of Omega 3 (DHA).
10mg of Inositol
20mg of Choline Bitartrate

For the full list of excipients, see section 6.1.

## 3. Pharmaceutical form

Oral Syrup

Milk colored syrup pleasantly flavored

## 4. Clinical particulars

### 4.1 Therapeutic indications

As essential nutrient GREENVINE DHA is indicated to restore the balance between the Omega-6 and the Omega-3 fatty acids.

The most beneficial and most active of these fatty acids are EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid), which play a crucial role in the prevention of arteriosclerosis, heart attack, depression and cancer. Inositol is a sugar made in the body and found in foods. It can be found in nine forms. Myo-inositol and D-chiro-inositol are most common in supplements.

Inositol might balance certain chemicals in the body to help with mental conditions such as panic disorder, depression, and obsessive-compulsive disorder. It might also help insulin workbetter.

People use inositol for metabolic syndrome, polycystic ovary syndrome (PCOS), and for reducing the risk of preterm birth. It's also used for insomnia, bipolar disorder, PTSD, and many other conditions, but there is no good scientific evidence to support most of these uses. Brain health support is the primary reason to take choline bitartrate supplements, due to choline's role in the biosynthesis of acetylcholine, therefore it is a prominent ingredient in GREENVINE DHA,

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Choline is also featured because it supports healthy inflammation management, heart health and liver health.

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Omega 3 fatty acids are beneficial to everybody, and a daily intake is recommended to improve health and development. Docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) are essential fatty acids which are important for a proper development associated with :

- Increase in birth weight and decrease in the risk of premature birth.
- Improvement of brain development, and of visual development.
- Protection of the skin from aging.
- Support of the immune system.
- Support of heart and blood pressure
- Improvement of the metabolism.
- Increase in flexibility of the joints.
- Improvement of emotional well-being and positive mental outlook; decrease of stress.

**4.2 Posology and method of administration**

**Posology**

**Babies (0 – 6months):**

5ml (1 teaspoonfuls) daily

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**Children (7months – 5years):**

10ml (2 teaspoonful) daily

**Children (5years and above):**

15mls (3 teaspoonfuls) daily

**4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

- The use of aspirin and anti-coagulants such as warfarin is contra-indicated, because omega-3 fatty acids have an influence on the functioning of the blood platelets.
- Patients at high risk of bleeding.

**4.4 Special warnings and precautions for use**

Since fish oils are derived from marine life, allergic reactions are possible. Use of the product has to be interrupted if rash or other allergic reactions are observed. Patients should be advised to consult a doctor immediately.

*Disorders of liver and kidneys*

Studies have shown that the dietary supplementation with fish oil improves the renal function of normal subjects, as well as that of patients with renal failure of different aetiologies.

Administration of fish oil for 1 month was unable to improve renal function in cirrhotic patients with ascites and renal failure. The occurrence of undesirable effects, such as the reduction of arterial pressure and the prolongation of bleeding time, argues against the use of fish oils in these patients.

**4.5 Interaction with other medicinal products and other forms of interaction**

Some studies reported that some important bleeding occurred when fish oil was combined with aspirin or warfarin.

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## 4.6 Fertility, pregnancy and lactation

**Fertility**

Animal studies support the role of omega-3 fatty acids in the reproduction mechanism.

**Pregnancy**

EPA and DHA fatty acids are administrated as supplement in the diet for pregnant women. They have a positive influence on the development of the foetus during the last three months of the pregnancy.

**Lactation**

EPA and DHA fatty acids are administrated as supplement in the diet for lactating women. GREENVINE DHA has a positive influence on the new born during the lactating period.

## 4.7 Effects on ability to drive and use machines

On the basis of the product's pharmacodynamic profile and reported adverse events, GREENVINE DHA has no known effect on an individual's ability to drive or operate machinery.

## 4.8 Undesirable effects

The following serious adverse reactions require the attention of a doctor or healthcare professional:

- mood changes or emotions,
- easy bruising,
- rash, or unusual skin reactions.

Most common undesirable effects are gastrointestinal disorders, such as nausea or dyspepsia.

Uncommon, rare to very rare undesirable effects:

- bad breath (fish breath),
- belching,
- diarrhoea,
- heartburn,

- stomach upset,
- weight gain.

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

### 4.9 Overdose
**Symptoms**

No cases of overdose have been reported.
In case of overdose, there are no particular recommendations. Symptomatic treatment must be put in place.

## 5. Pharmacological properties
### 5.1 Pharmacodynamic properties

The omega-3 polyunsaturated fatty acids , eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are essential fatty acids.
The exact mechanism of action of omega-3-carboxylic acids is unknown. However, possible mechanisms include: increased liver mitochondrial beta-oxidation, increased plasma lipoprotein lipase activity, inhibition of acyl-CoA: 1, 2-diacylglycerol acyltransferase, and decreased liver lipogenesis.
Furthermore, omega-3-carboxylic acids may decrease the production of liver triglycerides because they are poor substrates for the enzymes that participate in triglyceride synthesis, and they inhibit esterification of other fatty acids.

Vitamin E appears to act as an anti-oxidant within membranes, preventing propagated oxidation of unsaturated fatty acids.

## 5.2 Pharmacokinetic properties

*Absorption*

Following oral administration, polyunsaturated fatty acids (PUFAs) are absorbed normally as food substances at the normal food rate. EPA takes 5 to 8 hours to achieve peak concentration . DHA takes 5 to 9 hours to achieve peak concentration.

*Distribution*

Eicosanoids are localised tissue hormones. They do not travel in the blood, but are created in the cells. EPA and DHA are mainly bound to phospholipids.

Vitamin E enters the blood via the chylomicrons in the lymph and is bound to beta- lipoproteins. It is widely distributed to all tissues, and stored in adipose tissue.

*Metabolism*

The liver is the primary metabolism site. EPA and DHA are primarily oxidised in the liver similar to fatty acids derived from the diet.

Some vitamin E is metabolised in the liver to glucuronides of tocopheronic acid and its γ-lactone.

Omega-3 and omega-6 fatty acids share the same pools of enzymes and go through the same oxidation pathways while being metabolised. Once ingested, alanine (ALA) and linolenic acid (LA) can be elongated and desaturated into Long chain (LC) PUFAs. LA is converted into gamma-linolenic acid (GLA, 18:3 n-6), an omega-6 fatty acid that is a positional isomer of ALA. GLA, in turn, can be converted to the long-chain omega-6 fatty acid, arachidonic acid (AA, 20:4 n-6). ALA can be converted, to a lesser extent, to the long-chain omega-3 fatty acids, eicosapentaenoic acid (EPA; 20:5 n-3) and docosahexaenoic acid (DHA; 22:6n-3). However, the conversion from parent fatty acids into LC PUFAs occurs slowly in humans, and conversion rates are not well understood.

*Elimination*

After beta-oxidation the unsaturated fatty acids are following the elimination pathway of normal food substances.

Omega-3-carboxylic acids are not excreted via the kidneys. The total body clearance of EPA is 548 ml/h ; the total body clearance of DHA is 518 ml/h and. The elimination half-life of EPA is 37 hours ; the elimination half-life of DHA is 46 hours.

Some vitamin E is excreted in the urine, but most of a dose is slowly excreted in the bile.

## 5.3 Preclinical safety data

*General toxicity*

Three times the maximum safe daily dosage only shows an increase in cholesterol and HDL and no interference with other function.

Acutely and chronically, there were no differences in external appearance, level of activity, daily food consumption, blood cell count, kidney function, thyroid function, prothrombin time (PT), and activated partial prothrombin time (PTT), which remained within normal ranges.

*Reproductive toxicity*

Results of a recent study indicated that supplementing bull semen extender with n-3 fatty acid and α-tocopherol improved post-thawed in vitro characteristics of Brown Swiss bull sperm.

In humans, clinical studies showed that dietary omega-3 supplementation increased sperm concentration, motility, and morphology, and also antioxidant activity in human seminal fluid.

# 6. Pharmaceutical particulars

## 6.1 List of excipients

Microcrystalline cellulose and carmellose sodium

Sucrose

Methyl paraben

Propyl paraben

Sorbitol liquid 70%

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**6.2 Incompatibilities**

None.

**6.3 Shelf life**

3 years

**6.4 Special precautions for storage**

Keep the container tightly closed to protect from light, moisture and store below 30°C.

**6.5 Nature and contents of container**

An amber coloured 200ml glass bottle with CRC cap.

**Pack sizes** 200ml.

**6.6 Special precautions for disposal and other handling**

No special instructions.

**7. Marketing authorisation holder**

Jehyson Healthcare Limited, JehysonCrescent,
Ewekoro, Ogun State.

**8. Manufacturer**

Greenvine Pharmaceuticals Limited, Lagos.

**9. Date of first authorisation/renewal of the authorisation**

NA

**10. Date of revision of the text**

NA