**Package leaflet: Information for the patient**

**Fortaline® Plus *Oral solution***

***Omega-3 fish oil syrup***

**Please read this leaflet carefully before taking this medicine because it contains important information for you. Keep this leaflet. You may need to read it again.**

* **If you have any further questions, ask your doctor or pharmacist.**
* **If you notice any side effects, talk to your doctor or pharmacist.**

1. **What Fortaline® Plus *Oral solution* is and what it is used for.**

One teaspoon (5 ml) of Fortaline® Plus *Oral solution* contains 4.5 g of fish oil (1.5 g of omega-3 [DHA/EPA 18/11]), lemon flavour, a mixture of antioxidants based on ascorbyl palmitate (a source of vitamin C), tocopherol-rich extracts (vitamin E) and rosemary extracts (ATC code: C10AX06).

Fortaline® Plus *Oral solution* is used for:

Omega-3 fatty acids have beneficial effects for everyone and taking them daily is recommended for improving health and development. Docosahexaenoic (DHA) acid and eicosapentaenoic acid (EPA) are essential fatty acids, which cannot be synthesized by the body in sufficient quantities. EPA and DHA are important for optimal development.

Some of these beneficial effects of omega-3 fatty acids are listed below:

* Increases birth weight (due to a better quality of cells).
* Decreases the risk of premature birth.
* Improves cerebral development.
* Improves visual development.
* Protects the skin against aging.
* Supports the immune system.
* Supports the heart and blood pressure.
* Improves your metabolism and flexibility of the joints.
* Improves the sense of well-being and positive mental attitude.
* Reduces stress.

Although useful for everyone, the composition of Fortaline® Plus *Oral solution* is specifically adapted to the needs of pregnant women and pre-school age children.

1. **What you need to know before you take Fortaline® Plus *Oral solution***.

* Do not take Fortaline® Plus *Oral solution* if you are allergic to ingredients in Fortaline® Plus *Oral solution*.
* As fish oils are extracted from marine organisms, allergic reactions may occur. Use of this product should be discontinued if you have an allergic reaction. You should consult your doctor immediately.
* If you have to undergo surgery, tell your doctor that you are taking fish oil before scheduling the surgery.
* The only possible interactions with omega-3 fatty acids are interactions with anticoagulants and aspirin which could, in theory, emphasize the decrease in blood viscosity.
* Fortaline® Plus *Oral solution* is beneficial for pregnant and nursing women, and it is also an excellent choice for women who are actively trying to become pregnant. Scientific studies show that pregnant women do not have enough omega-3 fatty acids in their diet.

1. **How to use Fortaline® Plus *Oral solution***.

* A daily intake of 5 ml (one teaspoon) is highly recommended for children. Adults can take up to 10 ml.
* It is recommended to take this product with food or during meals to avoid an upset stomach.

1. **Possible side effects.**

***The following adverse effects should be reported as soon as possible to your doctor or a healthcare professional:***

* mood swings, appearance of bruises following mild trauma, skin rash or unusual skin reaction.

***The following adverse effects do not require immediate medical attention*** *(inform your doctor or a healthcare professional of these effects if they persist or become troublesome):*

* bad breath (fishy breath), belching, diarrhea, heartburn.

1. **How to store Fortaline® Plus *Oral solution***.

* Store at a temperature not exceeding 30°C in the original packaging, away from air, heat and light. Keep out of reach and sight of children.
* Do not freeze. Close bottle tightly. Do not keep the product beyond the expiration date indicated on the packaging.

1. **Contents of the pack:**

* Fortaline® Plus *Oral solution* is supplied in a glass bottle containing 100 ml of omega-3 fish oil syrup.

1. **Manufacturer’s name:** Marine Ingredients AS, Strandgata 60, 6270 Brattvag, Norway.
2. **Marketing Authorisation Holder:** Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.
3. **Date on which leaflet was revised:** November 2015.