SUVEAL IRON PREGNANCY

Premium once a day pregnancy supplement to provide high dietary intakes of essential nutriments
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PRODUCT DESCRIPTION

Name of the product:
SUVEAL IRON PREGNANCY
30 caps

Status:
Food supplement

Use in case of

• Planning conception
• Pregnancy

Composition:

• Nutritional facts

<table>
<thead>
<tr>
<th></th>
<th>Per caps</th>
<th>% RDA*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish oil EPAX</td>
<td>236 mg</td>
<td></td>
</tr>
<tr>
<td>including Omega 3:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DHA (101 mg) and EPA (26 mg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iron Bisgyciante</td>
<td>70 mg</td>
<td></td>
</tr>
<tr>
<td>Incleded Iron</td>
<td>14 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Zinc</td>
<td>10 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Iodine</td>
<td>150 µg</td>
<td>100%</td>
</tr>
<tr>
<td>Selenium</td>
<td>50 µg</td>
<td>90%</td>
</tr>
<tr>
<td>Chrome</td>
<td>40 µg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>80 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>12 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin B3</td>
<td>16 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin B5</td>
<td>6 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>1,4 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin B2</td>
<td>1,4 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin B1</td>
<td>1,1 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin B9</td>
<td>400 µg</td>
<td>200%</td>
</tr>
<tr>
<td>Vitamin D3</td>
<td>5 µg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>2,5 µg</td>
<td>100%</td>
</tr>
</tbody>
</table>

* RDA: Recommended Daily Allowance
**Ingredients**

Wild Fish Oil EPAX QS, scales fish gelatin, sunflower oil, humectant: glycerol, iron bisglycinate (maltodextrin), ascorbic acid (vitamin C), thickener: yellow beeswax, zinc sulfate microencapsulated, nicotinamide (Vitamin B3), acetate, d-alpha tocopherol (natural vitamin E), calcium D-pantothenate (vitamin B5), emulsifier: rapeseed lecithin, cyanocobalamin (Vitamin B12) (maltodextrin), color : black iron oxide, pyridoxine hydrochloride (vitamin B6), riboflavin (vitamin B2), thiamine mononitrate (Vitamin B1 mononitrate), color : red iron oxide, Folic Acid (Vitamin B9), cholecalciferol (vitamin D3), chromium chloride, potassium iodide, sodium selenite.

**Packaging:**

Box of 30 soft caps of 827mg.

**Directions for use:**

Take every day as directed:
1 soft capsule swallowed daily during a meal, throughout pregnancy

**Warnings:**

Do not exceed the recommended daily dose.

Food supplements should be used as part of a healthy lifestyle and should not be used as a substitute for a varied and balanced diet.
Keep out of reach of children.

**Contraindication:**

None

**Conservation:**

Shelf life of 36 months
Store at room temperature

**Fabricant:**

Laboratoire Densmore
7 rue de Millo – 98000 MONACO
2. SAFETY AND EFFICACY

Scientific context

Several epidemiological investigations including the French “Val de Marne” study and “Suvimax” study (Hercberg 1991, Bertrais 2004) showed that a non negligible part of the population receives intakes below the recommendations and / or shows signs of deficits in several vitamins and minerals. It showed that most of the pregnant women already show a deficit before conception even though their need will increase during pregnancy.

Data reports that nutrient intakes during pregnancy affect the health and growth of children. The organic immaturity of embryo and foetus makes them particularly sensitive to environmental nutritional disorders. It is well established that tissue differentiation is related to the quality and quantity of nutritional inputs such as glucose, fatty acids, amino acids, iron, and vitamins.

Pregnancy is the scene of an adaptation of the organism to promote optimal fetal development and breastfeeding. Despite the many metabolic adjustments, some deficiencies or excesses can be harmful to the mother and / or child. Supplementation of pregnant woman is therefore critical. The increased needs for vitamins and minerals during pregnancy may result in a deficiency of folic acid (vitamin B9) or iron in the baby. The first is especially important in early pregnancy and its lack would result in birth defects. A lack of the latter may cause risk of prematurity and fetal growth delays.

The Suvéal® Iron Pregnancy formula has been established to cover 100% of the recommended daily intakes for pregnant women in vitamins and minerals (200% for folic acid as recommended by public health institutes) and to provide polyunsaturated fatty acids which are critical to the brain development of the child (Morse 2012). The main objective of this supplementation is to cover iron deficiencies thanks to a good digestibility of the form used. Indeed, compliance is generally low for iron-based supplements because of negative gastrointestinal side effects. Our formula has been specially designed with the most bioavailable form for an optimal digestibility.
Role of the components

- Minerals
  - Iron

Iron needs are greatly increased during pregnancy (6 times). It is involved in the structure of hemoglobin, myoglobin and in several metabolic reactions such as mitochondrial electron transport, catecholamine metabolism and DNA synthesis (Lukianova 2005).

Iron deficiency during pregnancy affects more than 2/3 of pregnant women, causing anemia in 20 to 30% of them and ultimately increasing risks of preterm delivery and low birth weight (Imdad 2012). It is worth noting that risks are greater in multiple pregnancies.

A routine supplementation of pregnant women to reach the recommended daily intake is recommended (Ulvik 2013). The form chosen is crucial given the general low compliance due to possible gastrointestinal side effects such as diarrhea or constipation. The form chosen in the Suveal® formula is iron bisglycinate, which is better absorbed and tolerated by the body. The iron bisglycinate has a low molecular weight, is electrically neutral, non-ionizing and less reactive and is a ligand well metabolizable by the body. Given to this form, the iron after absorption has no interaction with the others components of the soft capsules. The studies show that the absorption of bisglycinate iron is 3-4 times greater than iron sulfate (form found in the most of the food supplement for pregnancy) (Layrisse 2000). Its bioavailability is 4 times greater than iron sulfate (Bovell-Benjamin 2000) and its efficacy is significantly better than iron sulfate in the control of iron deficiency in pregnant women (Szarfarc 2001). One of the most important point with this form of iron is that it limits the side effects like diarrhea and constipation with a better digestive tolerance proved in studies (Coplin 1991).

- Iodine

Iodine is essential to the structure of the two thyroidal hormones T3 and T4, which control the whole cell maturation process and particular major operations such as thermogenesis, transcriptional modulation of protein synthesis, and carbohydrates and lipids homeostasis.

The impact of a lack of supply during pregnancy is related to the consequences of hypothyroidism: spontaneous abortions, perinatal...
mortality, low birth weight. Implications on thyroid function and neurological development of the fetus may also be expected (Glioner 2003, Skeaff 2011). The specific supplementation of pregnant women early in pregnancy prevents or reduces functional and morphological thyroid abnormalities in mother and child (Glioner 2007, Morse 2012).

- **Other minerals**
  
  Zinc supplementation during pregnancy will have a positive effect on cell growth and neuronal maturation (Yu 2013). Selenium has an immunomodulatory and antioxidant role (Mariath 2011) and chromium will help to prevent gestational diabetes and glucose intolerance, thereby controlling weight gain during pregnancy (Institute of Medicine 2001, Picciano 2003).

- **Vitamins**
  - **Vitamin B9**
    
    In general, deficiencies of folic acid for women of childbearing age come from a lack of food intake and increased requirement (consumption of low calorie diets, hormonal contraception, tobacco, alcohol). Public health authorities emphasize the need to supplement would-be pregnant women in vitamin B9 (400 µg/day) in order to prevent risks of default of neural tube closure (DNTC).

    In the first weeks of pregnancy, folic acid deficiency can cause a DNTC. As the neural tube closes in the fourth week of embryonic life it’s imperative to start supplementation as soon as possible (Wilson 2007). The supplementation in pregnant women reduces that risk by 72% (Czeizel 1992) and also reduces the risk of preterm birth (Czeizel 2000). As a result, public health institutes recommend a systematic folic acid supplementation to women planning to be pregnant. The Suvéal® formula brings the recommended daily dose of 400 µg of folic acid.

  - **Other vitamins**
    
    Vitamins B are involved in the development of brain and immune system of the newborn infant and on the energy metabolism of the mother (Elmadfa 2012).

    The need for Vitamin C is also increased during pregnancy due to hemodilution and active transport of this molecule in placenta and cord blood. Deficiencies in Vitamin C and E are associated with a risk of pre-
eclampsia (Klemmensen 2009) a lower absorption of iron (Halberg 1989) in pregnant women.

- **Fatty acids**

  The formula of Suveal Iron Pregnancy® provides 127mg of Omega 3 as EPA and DHA. This supplementation aims at decreasing the Ω3/Ω6 ratio that is generally too high in occidental women, without decreasing the status of Omega 6 that is critical to a lot of neural and cognitive functions.

  Increasing Omega 3 status is essential to ensure a proper development of the baby brain (Morse 2012). Studies showed that children of age 4 have higher IQ when the mother was supplemented in Omega 3 during the breastfeeding period, compared to no supplementation (Helland 2003). DHA is also of interest in improving visual acuity of the baby (SanGiovanni 2000, Hoffman 2004) and in mitigating the post-partum depression of the mother (Otto 2003, Llorente 2003, Martinez 2004).

**Goals of supplementation**

  Suveal® Iron Pregnancy is a specific formula covering all the recommended daily intakes for pregnant women of vitamins, minerals and polyunsaturated fatty acids with only one capsule a day. This contribution will help to ensure the proper development of the fetus, especially preventing risks of brain malformation and immune system disruptions, and to limit fatigue, weight gain and postpartum depression on the mother.
3. PROMOTIONAL MATERIAL

Suvéal®
GROSSESSE FER
100 % des Besoins Grossesse en Apports Supplémentaires Conseillés

- Fer absorption +++ sans troubles digestifs
- Oméga 3 protégés : pas de reflux d’huile de poisson
- Limite la fatigue
- Renforce l’Immunité
- Favorise la synthèse du collagène

Alimentation : 1 dosière x 30 capsules

<table>
<thead>
<tr>
<th>Nutrimétrie</th>
<th>Dose par capsule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fer</td>
<td>17 mg Ferrozam hypochrome</td>
</tr>
<tr>
<td>Acide</td>
<td>100mg</td>
</tr>
<tr>
<td>C</td>
<td>60 mg</td>
</tr>
</tbody>
</table>

Etablie également en boîte de 30 et en formule sans fer

Boîte de 5 mois (60 capsules)
Code ACL : 340152645974

Suvéal®
Compléments alimentaires
Gamme gynécologie

DENSMORE
9/13         July 2014
Suvéal® IRON PREGNANCY

Premium pregnancy supplement once a day to provide high dietary intake of essential nutrients

KEY FEATURES & BENEFITS
- Complete formula mainly rich in iron, iodine, folic acid, ω3 fatty acid
- High quality labels
- Best safety: bovine and porcine free, gluten-free, allergen free, purified oil from fish with scales
- Easily digestible (gallenic formulation)

USE IN CASE OF:
- Planning conception
- During pregnancy

ACTIVE INGREDIENTS

Status: Food supplement
Box of 30 or 90 caps

Instructions for Use:
1 soft capsule daily, (taken at breakfast with a glass of water)
4. REFERENCES


