

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS

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### 1 NAME OF THE MEDICINE

LACTOCARE

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

#### Component 1: Multivitamin and mineral tablet contains:

| Ingredients  | Per tablet       |
|--|------------------|
| Calcium (from calcium carbonate and calcium phosphate dibasic) | 150 mg           |
| Phosphorus (from calcium phosphate dibasic)                    | 31,42 mg         |
| Vitamin C (as ascorbic acid)                                   | 75 mg            |
| Magnesium (from magnesium oxide)                               | 30 mg            |
| Vitamin B3 (as nicotinamide)                                   | 20 mg            |
| Zinc (from zinc oxide)   | 20 mg            |
| Iron (from iron II bisglycinate 20%)                           | 15 mg            |
| Glycine (from iron II bisglycinate 20%)                        | 5,52 mg          |
| Choline (from choline bitartrate 1 %)                          | 10,3 mg          |
| Vitamin B5 (from calcium-d-pantothenate)                       | 7 mg             |
| Calcium (from calcium-d-pantothenate)                          | 0,8 mg           |
| Vitamin B1 (from thiamine mononitrate)                         | 2 mg             |
| Vitamin B2 (as riboflavin)                                     | 2 mg             |
| Vitamin B6 (from pyridoxine hydrochloride)                     | 2 mg             |
| Copper (from copper glycinate 10%)                             | 1 mg             |
| Glycine (from copper glycinate 10%)                            | 0,35 mg          |
| Vitamin A (from vitamin A acetate 325000 IU/g)                 | 2 666 IU         |
| Vitamin D3 (as cholecalciferol)                                | 200 IU<br>(5 µg) |
| Folic acid   | 500 µg           |
| Selenium   | 60 µg            |
| Biotin   | 35 µg            |
| Vitamin B12 (as cyanocobalamin 0,1 %)                          | 2,8 µg           |

#### Component 2: Each Omega-3 soft gel capsule contains:

| Ingredients  | Per capsule |
|--|-------------|
| Total Pharmaceutical Grade Fish oil, from tuna and deep marine fish oil providing: | 823 mg      |
| Docosahexaenoic Acid (DHA)   | 261 mg      |
| Eicosapentaenoic Acid (EPA)  | 92 mg       |

For full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Component 1: Multivitamin and Mineral Tablet: Oval, purple/magenta, film-coated tablet.

Component 2: Omega-3 Soft Gel Capsule: Oblong, clear yellow, soft gel capsule.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indication

LACTOCARE is a health supplement for women which provides nutritional support during breastfeeding.

#### 4.2 Posology and method of administration

Take one multivitamin and mineral tablet (purple) and one omega-3 soft gel capsule (clear yellow capsule) daily with food, or as directed by a healthcare provider.

The daily dosage can be taken together, or incrementally throughout the day.

The dosage remains the same for multiple (twins, triplets, etc) pregnancies.

#### 4.3 Contraindications

Do not take LACTOCARE if you are hypersensitive to any of the active or inactive ingredients.

#### 4.4 Special warnings and precautions for use

- LACTOCARE should be used with caution in patients with haemorrhagic disorders or in patients using medication affecting blood coagulation, such as anticoagulants. (see **INTERACTIONS**)
- Use with caution in patients with hypercalcaemia or renal calculi.
- The omega-3 capsules contain small amounts of sorbitol and glycerol which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary condition of sorbitol or glycerol intolerance should not take this medicine.

#### 4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on LACTOCARE. The following interactions are noted on the monographs of the active ingredients:

- Antacids should be taken at least 2 hours before or after LACTOCARE, as they may reduce the absorption of vitamins and minerals.
- Anticoagulants/Antiplatelets: there is an increased risk of bleeding with concurrent use of medicines containing omega-3.

#### 4.6 Fertility, pregnancy and lactation

LACTOCARE is suitable for use before and during pregnancy and lactation at the recommended dose.

#### 4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

#### 4.8 Undesirable effects

Possible side effects are:

- gastrointestinal discomfort (nausea, vomiting, heartburn, abdominal pain, bloating, dyspepsia, diarrhoea, constipation)
- eructation (belching) associated with a fishy taste in the mouth

#### 4.9 Overdose

Symptoms of overdosage include stomach upset, nausea, diarrhoea or constipation.

Treatment is symptomatic and supportive.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement

D34.12 Multiple substance formulation

### 5.2 PHARMACOLOGICAL ACTION

- Vitamin A contributes to the maintenance of good eyesight, skin, membranes and immune function.
- The B Vitamins help to metabolise carbohydrates, fats and proteins, contribute to normal psychological function, normal functioning of the nervous system, maintenance of normal mucous membranes, maintenance of normal skin, regulation of hormonal activity, normal function of the heart, and the reduction of tiredness and fatigue.
- Vitamin C is an antioxidant for the maintenance of good health. It contributes to cell protection from free radical damage, helps in the development and maintenance of bones, cartilage, teeth and gums and helps with connective tissue formation.
- Calcium and Vitamin D contribute to the maintenance of normal muscle function and help in the development of healthy bones and teeth.
- Folic Acid contributes to maternal tissue growth during pregnancy and helps to reduce the risk of neural tube defects when taken daily prior to becoming pregnant and during early pregnancy.
- Iron helps with the formation of healthy red blood cells which play a role in oxygen transport in the body.
- Omega-3 contains Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA) which help to support cognitive health and brain function.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Multivitamin and mineral tablet: croscarmellose sodium, copovidone, magnesium stearate, microcrystalline cellulose and purified water.  
Coating: castor oil, flexicoat violet, shellac.

Omega-3 softgel capsule: alpha-tocopherol (covitol), gelatine (bovine), lemon flavour, simethicone, purified water. Contains sugar: glycerol 0,11 g and sorbitol 0,013 g/capsule.

### **6.2 Incompatibilities**

Unknown

### **6.3 Shelf life**

2 years

### **6.4 Special precautions for storage**

Store at or below 25 °C. Store blister strips in the outer carton to protect from sunlight and moisture.  
KEEP OUT OF THE REACH OF CHILDREN.

### **6.5 Nature and contents of container**

30-day pack containing 6 blisters with 15 tablets/capsules per blister.

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

No special requirements

## **7 HOLDER OF CERTIFICATE OF REGISTRATION**

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## **8 REGISTRATION NUMBER**

To be allocated.

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

## **9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION**

September 2020