

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

PRIMEVE PLUS (capsules)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per Capsule
<i>Oenothera biennis</i> (Evening Primrose Oil) [Part: seed] Providing: Linoleic Acid Gamma-Linoleic Acid	350 mg 210 mg 27 mg
Magnesium (Magnesium oxide)	60 mg
Vitamin B6 (Pyridoxine Hydrochloride)	24 mg
Vitamin E (d-Alpha-Tocopherol)	15 IU
Zinc (Zinc oxide)	4 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

PRIMEVE PLUS capsules are oblong, lilac soft gel capsule, filled with a white paste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

PRIMEVE PLUS provides essential fatty acids, vitamins and minerals for the maintenance of good health.

4.2 Posology and method of administration

Adults over 18 years: Take 1 – 4 capsules daily with meals, or as recommended by a healthcare provider.

Adolescents 14 – 18 years: Take 1 – 3 capsules daily with meals, or as recommended by a healthcare provider.

Children 9 - 13 years: Take 1 – 2 capsules daily with meals, or as recommended by a healthcare provider.

The dose can be adjusted to your needs i.e. you can take 1 capsule daily and increase the dose as required in times when you need additional support (e.g. the week before menstruation).

4.3 Contraindications

Do not use PRIMEVE PLUS:

- if you are hypersensitive to any of the ingredients, including the excipients.
- in patients with psychiatric or mental disorders such as schizophrenia or bipolar disorder (see Section 4.4)
- in patients with temporal-lobe epilepsy (see Section 4.4)
- in children under the age of 9 years.

4.4 Special warnings and precautions for use

- Use with caution in patients with haemorrhagic disorders or in patients using medication affecting coagulation, such as anticoagulant or antiplatelet medicines.
- Use with caution in patients with breast cancer.
- Patients undergoing elective surgery should discontinue use of PRIMEVE PLUS at least 2 weeks prior to the surgery.
- Use with caution in schizophrenic patients and/or patients receiving eleptogenic medicines such as phenothiazines, (see Section 4.5) as it may have the potential to manifest undiagnosed temporal lobe epilepsy.
- Contains small amounts of sorbitol and glycerol which may have an effect on the glycaemic control of patients with *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 PRIMEVE PLUS. The following are noted in the monographs of the active ingredients:

Anticoagulants: PRIMEVE PLUS may enhance the anticoagulant effect of warfarin, long-term aspirin, or any other blood thinning medicines.

Calcium channel blockers: concurrent use of PRIMEVE PLUS may enhance their effect.

Phenothiazines: Risk of seizure may be increased.

Potassium sparing diuretics: PRIMEVE PLUS may cause increased magnesium levels.

Magnesium in PRIMEVE PLUS can prevent the absorption of some medicines such as bisphosphonates (used for treatment of osteoporosis), digoxin (heart medication), gabapentin (anti-epileptic), levodopa/carbidopa (use in the treatment of Parkinson's disease), quinolones (antibiotic) and tetracyclines (antibiotic). It is advisable to take PRIMEVE PLUS 4 hours before or after these medicines.

4.6 Fertility, pregnancy and lactation

Safety of PRIMEVE PLUS has not been established during pregnancy and lactation.

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 irritation (nausea, vomiting, diarrhoea, flatulence)
- headache

4.9 Overdose

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

- Evening Primrose Oil is a source of essential fatty acids linoleic acid and gamma-linolenic Acid.
- Magnesium contributes to normal electrolyte balance; the maintenance of normal muscle function; the development and maintenance of bones and teeth; normal protein synthesis and has a role in the process of cell division.
- Vitamin B6 helps to metabolise carbohydrates, fats and proteins; contributes to normal functioning
- of the nervous system; the reduction of tiredness and fatigue; the regulation of hormonal activity and contributes to normal psychological function.
- Vitamin E functions as a tissue antioxidant thereby maintaining healthy cells.
- Zinc is an essential element which contributes to the maintenance of immune function and the maintenance of normal skin.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The excipients include beeswax, cochineal red (colourant), gelatine, iron oxide black (colourant), lecithin, purified water, simethicone, titanium dioxide (colourant) and unsaturated oil. Contains sugar: sorbitol 0,011 g and glycerol 0,09 g per capsule

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Store blisters in the carton to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Blister packs of 30, 60 and 90 capsules.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, 2007

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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