



**PROPRIETARY NAME (and dosage form):**

**Essentiale® Extreme (capsules)**

**COMPOSITION:**

Each hard gelatin capsule contains:  
De-oiled enriched phospholipids from soya-beans 300 mg

**PHARMACOLOGICAL CLASSIFICATION:**

Western Herbals: D 32.2 Other

**PHARMACOLOGICAL ACTION:**

The hepato-protective effects of phospholipids have been studied in numerous experimental models. Phospholipids accelerate membrane regeneration and stabilisation, inhibit lipid peroxidation and inhibit collagen synthesis.

The chemical structure of the phospholipids supplied with Essentiale® Extreme corresponds to that of the endogenous phospholipids, but they are superior to the latter because of their high content in polyunsaturated (essential) fatty acids.

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

**INDICATIONS:**

Essentiale® Extreme capsules is a herbal preparation to aid liver function. Essentiale® Extreme capsules provide support to the liver.

**CONTRA-INDICATIONS:**

Known hypersensitivity to soya-bean preparations or to any of the excipients.

**INTERACTIONS:**

An interaction of Essentiale® Extreme with anticoagulants cannot be excluded. Dose adjustment of the anticoagulant may be necessary. Patients are advised to consult a doctor in the case of simultaneous application.

**PREGNANCY AND LACTATION:**

Safety in pregnancy and lactation has not been established

**DOSAGE AND DIRECTIONS FOR USE:**

Adults and children from 12 years: 2 capsules three times daily with meals.

Essentiale® Extreme is taken (unchewed) with meals and plenty of liquid (e.g. with a glass of water).

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

Occasionally the administration of Essentiale® Extreme may cause gastrointestinal disorders, such as stomach complaints, soft stool and diarrhoea.

On very rare occasions allergic reactions may occur, such as exanthema and urticaria.

**SPECIAL WARNINGS AND PRECAUTIONS FOR USE:**

**Use of Essentiale® Extreme should be avoided by persons allergic to soya-bean oil.**

Protection against the intoxicating effects of alcohol has not been established with Essentiale® Extreme.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

There are no known cases of overdosage with Essentiale® Extreme capsules.

Treatment is symptomatic and supportive.

The patient should consult a doctor who may decide about the severity and any measures that might be necessary.

**IDENTIFICATION:**

Khaki, opaque, oblong, hard-gelatin capsules.

**PRESENTATION:**

Blister packs and / or securitainers of 5, 6, 10, 12, 20, 24, 50, 56, 100, 250 and 600 capsules. (Blister: PVC foil sealed with aluminium foil).

All pack sizes may not be marketed.

**STORAGE INSTRUCTIONS:**

Store in the original container, at or below 25°C.

**KEEP OUT OF REACH OF CHILDREN.**

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Winthrop Pharmaceuticals. (Pty) Ltd  
2 Bond Street, Midrand, 1685, South Africa.