Professional Information for ESSENTIALE 300 & 600

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

Essentiale 300 hard capsules

Essentiale 600 hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains:

Essentiale 300: phospholipids from soybeans 300 mg

Essentiale 600: phospholipids from soybeans 600 mg

Sugar free.

Excipients with known effect:

Contains soybean oil (see section 4.3).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsules.

Essentiale 300: Khaki, opaque, oblong, hard gelatine capsule.

Essentiale 600: Mahogany, opaque, elongated, hard gelatine capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Essentiale is used to improve subjective symptoms, such as loss of appetite or a feeling of pressure in the upper right abdomen, in patients with liver damage caused by metabolic-associated fatty liver disease.

4.2 Posology and method of administration

Posology

Adults and children from 12 years:

600 mg (2 **Essentiale 300** capsules or 1 **Essentiale 600** capsule) three times daily with meals.

Maximum daily dose is 1 800 mg.

Essentiale capsules should be swallowed whole (not chewed) with sufficient liquid (preferably 200 mL of water) during meals.

Method of administration

Oral use.

4.3 Contraindications

Hypersensitivity to phospholipids, soybean proteins, peanut or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Essentiale can cause severe allergic reactions, as it contains soybean oil.

The patient is advised in the patient information leaflet that the treatment of **Essentiale** is not a substitute for avoiding sources that may damage the liver (e.g. alcohol).

If the patient has chronic hepatitis, supportive treatment with **Essentiale** is only justified if an improvement in the subjective signs is observed under treatment. If the symptoms get worse or if other unclear symptoms appear, the patient should consult a medical practitioner.

4.5 Interaction with other medicines and other forms of interaction

An interaction of **Essentiale** with anticoagulants cannot be excluded. Dose adjustment of the anticoagulant may be necessary.

Patients are advised to consult a medical practitioner in the case of simultaneous use.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Essentiale has no influence on the ability to drive a vehicle and use machines.

4.8 Undesirable effects

System organ class	Frequency	Adverse reaction
Immune system disorders	Unknown	allergic reaction
Gastrointestinal disorders	Unknown	stomach disorders, soft stools and/or diarrhoea
Skin and subcutaneous tissue disorders	Unknown	exanthema, urticaria, pruritus

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of **Essentiale** is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse reactions to:

- The Pharmacovigilance Unit at Pharmacovigialce unit at CFAO: chcsa-za-safety@cfao.com (email) or 011 7796700 (tel), or
- SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

There are no known cases of overdosage with **Essentiale** capsules.

Treatment is symptomatic and supportive.

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

5. PHARMACOLOGICAL PROPERTIES

Category and class: A 32.16 Other substances or agents. Others.

ATC Code: A05BP02.

5.1 Pharmacodynamic properties

In many experimental models of acute liver damage, such as damage from ethanol, alkyl alcohol, tetrachloromethane, paracetamol and galactosamine, liver protective effects have been reported among the pharmacodynamic properties of the substance.

In addition, inhibition of steatosis and fibrosis has also been observed in chronic models (ethanol, thioacetamide, organic solvents). The mechanism of action is assumed to be accelerated regeneration and stabilisation of membranes, and inhibition of lipid peroxidation and collagen synthesis. There are no specific studies available on pharmacodynamics in man.

5.2 Pharmacokinetic properties

Animal experiments on pharmacokinetics have shown that orally administered radiolabelled soybean phospholipids were over 90 % absorbed in the small intestine.
Most of the phospholipids were cleaved by phospholipase A into 1-acyl-lysophosphatidylcholine, approximately 50 % of which was reacylated immediately into polyunsaturated phosphatidylcholine during the absorption process in the mucosa of the small intestine.
The phosphatidylcholine reaches the blood through the lymph pathway and then passes into the liver in particular, mostly bound to HDL. Pharmacokinetic studies in man were conducted with ^{3}H and ^{14}C radiolabelled dilinoleoylphosphatidylcholine, among other substances. The choline residue was labelled with ^{3}H and the linoleic acid with ^{14}C.

Peak ^{3}H concentrations were reached between 6 and 24 hours and accounted for 19,9 % of the dose. The half-life of the choline component was 66 hours. Peak ^{14}C concentrations were reached between 4 and 12 hours and were 27,9 % of the dose. The half-life of this component was 32 hours. 2 % of the ^{3}H and 4,5 % of the ^{14}C markers were recovered in the faeces. 6 % of the ^{3}H and

only trace amounts of the ^{14}C markers were recovered in the urine. These results therefore show that more than 90 % of both isotopes were absorbed in the intestines.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule filling:

Alpha-tocopherol

Ethanol (ethyl alcohol) 96 %

Ethyl vanillin

Hard fat

Hydrogenated castor oil

4-metoxyacetophenone

Soybean oil.

Capsule shell:

Gelatine (from ruminant origin)

Iron oxide (E172) black

Iron oxide (E172) red

Iron oxide (E172) yellow

Purified water

Sodium laurilsulfate

Titanium dioxide (E171).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

- Store at or below 25 °C.
- Protect from light and humidity.
- Keep in original packaging until required for use.

6.5 Nature and contents of container

Essentiale 300

- Transparent poly(vinyl chloride) / silver aluminium poly(vinylidene chloride) (PVC / PVDC) blister strip or
- White opaque cylindrical polypropylene containers with white opaque polyethylene snap-on caps.

Essentiale 600

- Transparent poly(vinyl chloride) / silver aluminium poly(vinylidene chloride) (PVC / PVDC) blister strip or
- Transparent poly(vinyl chloride) / silver aluminium Aclar® (polychlorotrifluoroethylene (PCTFE)) (PVC / Aclar®) blister strip.

Pack sizes: 5, 6, 10, 12, 20, 24, 50, 56, 100, 250 and 600 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicine should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CFAO Healthcare South Africa (Pty) Ltd

Atrium on 5th, 6th Floor,

Sandton City, Corner Maude and 5th Street,

Sandton, Gauteng,

2146

8. REGISTRATION NUMBERS

Essentiale 300: 55/32.16/0737

Essentiale 600: 55/32.16/0738

9. DATE OF FIRST AUTHORISATION

11 February 2025

10. DATE OF REVISION OF THE TEXT

Not applicable.