PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

ESSENTIALE 300 hard capsules

ESSENTIALE 600 hard capsules

Phospholipids from soybeans

Sugar free.

Read all of this leaflet carefully because it contains important information for you.

Essentiale is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **Essentiale** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Essentiale** with any other person.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet

1. What **Essentiale** is and what it is used for
2. What you need to know before you take **Essentiale**
3. How to take **Essentiale**
4. Possible side effects
5. How to store **Essentiale**
6. Contents of the pack and other information.

1. What Essentiale is and what it is used for

Essentiale is used to improve certain 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.

2. What you need to know before you take Essentiale

Do not take Essentiale:

- If you are hypersensitive (allergic) to phospholipids, soybean proteins, peanut or any of the other ingredients of **Essentiale** (see section 6 for other ingredients).

Warnings and precautions

Take special care with Essentiale:

- If your symptoms worsen or if other unclear symptoms appear. If this occurs, you should consult your doctor.
- The use of **Essentiale** does not replace avoidance of substances that damage the liver (e.g. alcohol).
- If you have chronic liver inflammation (hepatitis), supportive treatment with **Essentiale** is only justified if you notice an improvement in your symptoms.

Other medicines and Essentiale:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

An interaction of anticoagulants, such as warfarin (used to prevent the blood from clotting) with **Essentiale** may occur. It may therefore be necessary to adjust the dosage of the anticoagulant.

If you are taking **Essentiale** at the same time as anticoagulants, you should inform your doctor.

Essentiale with food and drink:

Essentiale capsules should be swallowed whole (unchewed) with sufficient liquid (preferably 200 mL of water) during meals.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking

Essentiale capsules.

Safety in pregnancy and lactation has not been established.

Driving and using machines:

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

Essentiale contains soybean oil.

If you are allergic to peanut or soybeans, do not use **Essentiale**.

3. How to take Essentiale

Always take **Essentiale** exactly as described in this leaflet or as your pharmacist has told you.

Check with your doctor or pharmacist if you are unsure.

The usual dose for adults and children older than 12 years is 600 mg (two **Essentiale 300** capsules or one **Essentiale 600** capsule) three times daily with meals.

Please consult your doctor or pharmacist if you think that the effect of **Essentiale** capsules is too strong or too weak.

If you take more Essentiale than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you, whether there are any **Essentiale** capsules left or not.

If you forget to take Essentiale:

If you forgot to take a dose, take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Essentiale can have side effects.

Not all side effects reported for **Essentiale** are included in this leaflet. Should your general health

worsen or if you experience any untoward effects while taking **Essentiale**, please consult your health care provider for advice.

If any of the following happens, stop taking Essentiale and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- rash or itching.
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **Essentiale**. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

Frequency unknown:

- stomach disorders, soft stools and/or diarrhoea
- exanthema (a skin rash with fever), urticaria (hives), pruritus (severe itching of the skin).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report any side effects directly to the Pharmacovigilance unit at CFAO: chcsa-za-safety@cfao.com.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **Essentiale**.

5. How to store Essentiale

- Store at or below 25 °C.
- Protect from light and humidity.
- Keep in original packaging until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Essentiale contains:

The active substance is phospholipids from soybeans.

Other ingredients are:

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).

What Essentiale looks like and contents of the pack:

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

- 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: Mahogany, opaque, elongated, hard gelatine capsule.

- 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.

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

This leaflet was last revised

Date of registration: 11 February 2025

Date of revision: Not applicable.

Registration numbers

Essentiale 300: 55/32.16/0737

Essentiale 600: 55/32.16/0738

Access to corresponding Professional Information

www.essentiale.co.za

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S0

ESSENTIALE 300 harde kapsules

ESSENTIALE 600 harde kapsules

Fosfolipiede uit sojabone

Suikervry.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.

Essentiale is beskikbaar sonder ’n dokter se voorskrif, sodat jy ’n ligte ongesteldheid kan behandel. Jy moet **Essentiale** nogtans versigtig gebruik om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees om dit weer te lees.
- Moenie **Essentiale** met enigiemand anders deel nie.
- Vra jou apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is **Essentiale** en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy **Essentiale** neem
3. Hoe om **Essentiale** te neem
4. Moontlike newe-effekte
5. Hoe om **Essentiale** te bewaar
6. Inhoud van die verpakking en ander inligting.

1. Wat is Essentiale en waarvoor word dit gebruik

Essentiale word gebruik om sekere simptome te verbeter, soos verlies aan eetlus of ’n gevoel van drukking regs bo in die buikstreek, by pasiënte met lewerskade veroorsaak deur metabolisme-geassosieerde vettige lewersiekte.

2. Wat jy moet weet voordat jy Essentiale neem

Moenie Essentiale neem nie:

- Indien jy hipersensitief (allergies) vir fosfolipiede, sojaboonproteïene, grondbone of vir enige van die ander bestanddele van **Essentiale** is (sien afdeling 6 vir die ander bestanddele).

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met Essentiale:

- Indien jou simptome vererger of indien ander onduidelike simptome verskyn. Indien dit gebeur, moet jy jou dokter raadpleeg.
- Die gebruik van **Essentiale** beteken nie dat stowwe wat skadelik is vir die lewer (bv. alkohol) nie steeds vermy moet word nie.
- Indien jy chroniese lewerontsteking (hepatitis) het, word ondersteunende behandeling met **Essentiale** slegs geregverdig indien jy ’n verbetering in jou simptome opmerk.

Ander medisynes en Essentiale:

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisynes in.)

Wisselwerking mag voorkom tussen antikoagulante, soos warfarien (gebruik om te voorkom dat bloedklonte vorm) en **Essentiale**. Dit mag dus nodig wees om die antikoagulant se dosis daarvolgens aan te pas.

Indien jy **Essentiale** terselfdertyd as antikoagulante neem, moet jy jou dokter daaroor inlig.

Essentiale met kos en drinkgoed:

Essentiale kapsules moet heel ingesluk word (moenie kou nie) met genoeg vloeistof (verkieslik 200 mL water) tydens ’n maaltyd.

Swangerskap en borsvoeding:

Indien jy swanger is of borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te

raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy **Essentiale** kapsules neem.

Dit is nie bekend of dit veilig is om tydens swangerskap en borsvoeding te gebruik nie.

Bestuur van voertuie en gebruik van masjiene:

Essentiale het geen invloed op die vermoë om ’n voertuig te bestuur en masjiene te gebruik nie.

Essentiale bevat sojaboonolie.

Indien jy allergies is vir grondboontjies of sojabone, moet jy nie **Essentiale** gebruik nie.

3. Hoe om Essentiale te neem

Neem **Essentiale** altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou apteker vir jou gesê het. Vra gerus jou dokter of apteker indien jy onseker is.

Die gebruiklike dosis vir volwassenes en kinders ouer as 12 jaar is 600 mg (twee **Essentiale 300** kapsules of een **Essentiale 600** kapsule) drie keer daagliks met ete.

Indien jy dink dat die uitwerking van **Essentiale** kapsules te sterk of te swak is, raadpleeg jou dokter of apteker.

Indien jy meer Essentiale neem as wat jy moet:

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem altyd die medisynehouer met die etiket op saam met jou, ongeag of daar nog **Essentiale** kapsules oor is.

Indien jy vergeet om Essentiale te neem:

Indien jy vergeet het om ’n dosis te neem, neem dit sodra jy onthou. Moenie ’n dubbele dosis neem om te vergoed vir individuele dosisse wat oorgeslaan is nie.

4. Moontlike newe-effekte

Essentiale kan newe-effekte hê.

Nie alle newe-effekte wat vir **Essentiale** gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou verswak of indien jy enige ongunstige effekte ondervind terwyl jy **Essentiale** neem, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg.

Indien enige van die volgende voorkom, hou op om Essentiale te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk en asemhaling kan veroorsaak.
- uitslag of gejeuk.
- floute.

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ondervind, mag jy ’n ernstige reaksie op **Essentiale** gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Sê so gou as moontlik vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte waarvan die frekwensie onbekend is:

- maagversteurings, sagte stoelgang en/of diarree
- eksanteem (veluitslag met koors), urtikarie (galbulte), pruritus (erge gejeuk van die vel).

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker daaroor in.

Rapportering van newe-effekte

Indien jy enige newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingsblad gelys word nie.
Jy kan newe-effekte direk aan CFAO se Eenheid vir Farmakowaaksaamheid rapporteer deur ’n e-pos na chcsa-za-safety@cfao.com.
Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety-toepassing (Medsafety X SAHPRA) en e-rapporteringplatform (who-umc.org), wat op SAHPRA se webwerf beskikbaar is. Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die

veiligheid van **Essentiale** te verskaf.

5. Hoe om Essentiale te bewaar

- Bêre by of onder 25 °C.
- Beskerm teen lig en humiditeit.
- Hou in die oorspronklike verpakking totdat dit benodig word vir gebruik.
- BEWAAR ALLE MEDISYNES BUITE BEREIK VAN KINDERS.
- Moenie gebruik ná die vervaldatum wat op die karton gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) wegdoen nie.

6. Inhoud van die verpakking en ander inligting

Wat Essentiale bevat:

Die aktiewe bestanddeel is fosfolipiede uit sojabone.

Ander bestanddele is:

Kapsule-inhoud:

Alfa-tokoferol, etanol (etielalkohol) 96 %, etielvanillien, harde vet, gehidrogeneerde kasterolie, 4-metoksiasetofenoon, sojaboonolie.

Kapsuledop:

Gelatien (van herkouer oorsprong), swart ysteroksied (E172), rooi ysteroksied (E172), geel ysteroksied (E172), gesuiwerde water, natriumlourielsulfaat, titaandioksied (E171).

Hoe Essentiale lyk en inhoud van die verpakking:

Essentiale 300: Kakiekleurige, ondeursigtige, langwerpige, harde gelatienkapsule.

- Deurskynende poli(vinielchloried) / silwer aluminium poli(vinilideenchloried) (PVC/PVDC) stulpstrook, of
- Wit ondeursigtige, silindriese polipropileenhouers met wit ondeursigtige poliëtileen aanknipdoppies.

Essentiale 600: Bruinrooi, ondeursigtige, langwerpige, harde gelatienkapsule.

- Deurskynende poli(vinielchloried) / silwer aluminium poli(vinilideenchloried) (PVC/PVDC) stulpstrook, of
- Deurskynende poli(vinielchloried) / silwer aluminium Aclar® (polichlorotrifluoroëtileen (PCTFE)) (PVC/Aclar®) stulpstrook.

Verpakkingsgroottes: 5, 6, 10, 12, 20, 24, 50, 56, 100, 250 en 600 kapsules.

Nie al die verpakkingsgroottes word noodwendig bemark nie.

Houer van Registrasiesertifikaat

CFAO Healthcare South Africa (Edms.) Bpk.

Atrium on 5th, 6de Vloer, Sandton City

h.v. Maude en 5de Straat

Sandton, Gauteng

2146

Hierdie inligtingsblad is laas hersien

Datum van registrasie: 11 Februarie 2025

Datum van hersiening: Nie van toepassing nie.

Registrasienommers

Essentiale 300: 55/32.16/0737

Essentiale 600: 55/32.16/0738

Toegang tot die ooreenstemmende Professionele Inligting

www.essentiale.co.za