PATIENT INFORMATION LEAFLET

ESSENTIALE® EXTREME 300 mg

sanofi

SCHEDULING STATUS
S0

ESSENTIALE® EXTREME 300 mg
Phospholipids from soya-beans
Sugar free.

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

Class D: Complementary Medicine:
Discipline specific - 33.6 Western Herbals Medicine

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you
Essentiale® Extreme 300 mg is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to **Essentiale® Extreme 300 mg** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **Essentiale® Extreme 300 mg** with any other person.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet
1. What **Essentiale® Extreme 300 mg** is and what it is used for
2. What you need to know before you take **Essentiale® Extreme 300 mg**
3. How to take **Essentiale® Extreme 300 mg**
4. Possible side effects
5. How to store **Essentiale® Extreme 300 mg**
6. Contents of the pack and other information.

1. What Essentiale® Extreme 300 mg is and what it is used for
Essentiale® Extreme 300 mg is a discipline specific western herbal medicine indicated to support and aid liver function.
Essentiale® Extreme 300 mg 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 substances harmful to the liver as well as poor diet (toxic effects of certain foods) and in those with chronic liver inflammation.

2. What you need to know before you take Essentiale® Extreme 300 mg
Do not take Essentiale® Extreme 300 mg:
- if you are hypersensitive (allergic) to phospholipids, soya-bean proteins, peanut or any of the other ingredients of **Essentiale® Extreme 300 mg** (see section 6 for other ingredients).

Warnings and precautions
Take special care with Essentiale® Extreme 300 mg:
- If your symptoms worsen or if other unclear symptoms appear. If this occurs, you should consult your doctor.
- The use of **Essentiale® Extreme 300 mg** does not replace avoidance of substances that damage the liver (e.g. alcohol).
- If you have chronic liver inflammation (hepatitis), supportive treatment with **Essentiale® Extreme 300 mg** is only justified if you notice an improvement in your symptoms.

Other medicines and Essentiale® Extreme 300 mg:
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® Extreme 300 mg** may occur. It may therefore be necessary to adjust the dosage of the anticoagulant.
If you are taking **Essentiale® Extreme 300 mg** at the same time as anticoagulants, you should inform your doctor.

This medicine is not intended to diagnose, treat, cure or prevent any disease.

Essentiale® Extreme 300 mg with food and drink:
Essentiale® Extreme 300 mg 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® Extreme 300 mg** capsules.
Safety in pregnancy and lactation has not been established.

Driving and using machines:
Essentiale® Extreme 300 mg has no influence on the ability to drive a vehicle and use machines.

Essentiale® Extreme 300 mg contains soya-bean oil.
If you are allergic to peanut or soya-beans, do not use **Essentiale® Extreme 300 mg**.

3. How to take Essentiale® Extreme 300 mg
Always take **Essentiale® Extreme 300 mg** exactly as described in this leaflet or as your pharmacsit 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 (2 **Essentiale® Extreme 300 mg** capsules) three times daily with meals.

Please consult your doctor or pharmacist if you think that the effect of **Essentiale® Extreme 300 mg** capsules is too strong or too weak.

If you take more Essentiale® Extreme 300 mg 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® Extreme 300 mg** capsules left or not.
If you forget to take Essentiale® Extreme 300 mg:
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® Extreme 300 mg can have side effects.
Not all side effects reported for **Essentiale® Extreme 300 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Essentiale® Extreme 300 mg**, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking Essentiale® Extreme 300 mg 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® Extreme 300 mg**
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 Sanofi's Pharmacovigilance Unit at za.CHCdrugsafety@sanofi.com (email) or 011 256 3700 (tel).
You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting"** Form found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **Essentiale® Extreme 300 mg**.

5. How to store Essentiale® Extreme 300 mg
- Store at or below 25 °C.
- Protect from light and humidity.
- Keep in original packaging until required for use.
- KEEP 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® Extreme 300 mg contains:
The active substance is phospholipids from soya-beans.

Other ingredients are:
Capsule filling:
Alpha-tocopherol, ethanol (ethyl alcohol) 96 %, ethyl vanillin, hard fat, hydrogenated castor oil, 4-metoxyacetophenone, soya-bean 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® Extreme 300 mg looks like and contents of the pack:
Essentiale® Extreme 300 mg:
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.

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
Opella Healthcare South Africa (Pty) Ltd
4th Floor, Building I, Hertford Office Park, 90 Bekker Road, Midrand, 1652

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N/A

PASIËNTINLIGTINGSBLAD

ESSENTIALE® EXTREME 300 mg

sanofi

SKEDULERINGSTATUS
S0

ESSENTIALE® EXTREME 300 mg
Fosfolipiede uit sojabone
Suikervry.

Elke harde gelatienkapsule bevat:
300 mg ontvette, verrykte fosfolipiede uit sojabone

Klas D: Komplementêre Medisyne:
Dissipline-spesifiek – 33.6 Westerse Kruiemedisyne

Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie.

Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou
Essentiale® Extreme 300 mg is beskikbaar sonder 'n dokter se voorskrif, sodat jy 'n geringe ongesteldheid kan behandel. Jy moet **Essentiale® Extreme 300 mg** nietemin versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie **Essentiale® Extreme 300 mg** met enigiemand anders deel nie.
- Vra gerus jou apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is **Essentiale® Extreme 300 mg** en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy **Essentiale® Extreme 300 mg** neem
3. Hoe om **Essentiale® Extreme 300 mg** te neem
4. Moontlike newe-effekte
5. Hoe om **Essentiale® Extreme 300 mg** te bêre
6. Inhoud van die pak en ander inligting.

1. Wat is Essentiale® Extreme 300 mg en waarvoor word dit gebruik
Essentiale® Extreme 300 mg is 'n dissipline-spesifieke Westerse kruiemedisyne wat aangedui word om lewerfunksie te help en te ondersteun.
Essentiale® Extreme 300 mg word gebruik om sekere simptome te verbeter, soos verlies aan eetlus of 'n drukkende gevoel regs bo in die buik, by pasiënte met lewerskade veroorsaak deur stowwe wat skadelik is vir die lewer, sowel as swak dieet (toksiese effekte van sekere kossoorte) en by dié met chroniese lewerinflammasie.

2. Wat jy moet weet voordat jy Essentiale® Extreme 300 mg neem
Moenie Essentiale® Extreme 300 mg neem nie:

- indien jy hipersensitief (allergies) is vir fosfolipiede, sojaboonproteïene, grondbone of vir enige van die ander bestanddele van **Essentiale® Extreme 300 mg** (sien afdeling 6 vir die ander bestanddele).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met Essentiale® Extreme 300 mg:

- Indien jou simptome vererger of indien ander onduidelike simptome verskyn. Indien dit gebeur, behoort jy jou dokter te raadpleeg.
- Die gebruik van **Essentiale® Extreme 300 mg** beteken nie dat stowwe wat die lewer beskadig (bv. alkohol). nie meer vermy hoef te word nie.
- Indien jy chroniese lewerinflammasie (hepatitis) het, word ondersteunende behandeling met **Essentiale® Extreme 300 mg** slegs geregverdig indien jy 'n verbetering in jou simptome opmerk.

Ander medisyne en Essentiale® Extreme 300 mg
Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Wisselwerking mag voorkom tussen antikoagulante, soos warfarien (gebruik om te voorkom dat klonte in die bloed vorm) en **Essentiale® Extreme 300 mg**. Dit mag dus nodig wees om die antikoagulant se dosis aan te pas. Indien jy **Essentiale® Extreme 300 mg** terselfdertyd as antikoagulante neem, moet jy jou dokter daaroor inlig.

Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

Essentiale® Extreme 300 mg met kos en drinkgoed:
Essentiale® Extreme 300 mg 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 jou baba borsvoed, vermoed dat jy swanger kan wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy **Essentiale® Extreme 300 mg** kapsules neem.
Dit is nie bepaal of dit veilig is om tydens swangerskap en borsvoeding te gebruik nie.

Bestuur en die gebruik van masjiene:
Essentiale® Extreme 300 mg het geen invloed op die vermoë om te bestuur en masjiene te gebruik nie.

Essentiale® Extreme 300 mg bevat sojaboonolie.
Indien jy allergies is vir grondboontjies of sojabone, moet jy nie **Essentiale® Extreme 300 mg** neem nie.

3. Hoe om Essentiale® Extreme 300 mg te neem
Neem Essentiale® Extreme 300 mg altyd presies soos wat in hierdie inligtingsblad beskryf 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
(2 **Essentiale® Extreme 300 mg** kapsules) drie keer daagliks met ete.

Konsulteer asseblief jou dokter of apteker indien jy dink dat die effek van **Essentiale® Extreme 300 mg** kapsules te sterk of te swak is.

Indien jy meer Essentiale® Extreme 300 mg neem as wat jy behoort te neem:
In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem altyd die gemerkte medisynehouer saam met jou, of daar enige **Essentiale® Extreme 300 mg** kapsules oor is of nie.

Indien jy vergeet om Essentiale® Extreme 300 mg 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® Extreme 300 mg kan newe-effekte hê.
Nie alle newe-effekte wat vir **Essentiale® Extreme 300 mg** gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of indien jy enige ongunstige effekte ervaar terwyl jy **Essentiale® Extreme 300 mg** neem, raadpleeg asseblief jou dokter, apteker of gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om Essentiale® Extreme 300 mg te neem en sê onmiddellik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal:

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

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige reaksie op **Essentiale® Extreme 300 mg** 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 wat met onbekende frekwensie voorkom:

- maagversteurings, sagte stoelgang en/of diarree
- eksanteem ('n veluitslag met koors), urtikarie (korwe), pruritus (hewige gejeuk van die vel).

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

Rapportering van newe-effekte
Indien jy newe-effekte ervaar, bespreek dit met jou dokter, apteker of verpleegster.
Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingsblad gelys word nie.
Jy kan ook enige newe-effekte direk aan Sanofi se Farmakowaaksaamheideenheid rapporteer, by za.CHCdrugsafety@sanofi.com (e-pos) of 011 256 3700 (tel).
Jy kan ook newe-effekte aan SAHPRA rapporteer via die **"6.04 Vorm vir Rapportering van Ongunstige Geneesmiddelreaksies"** wat aanlyn by SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer, kan jy help om meer inligting oor die veiligheid van **Essentiale® Extreme 300 mg** te verskaf.

5. Hoe omEssentiale® Extreme 300 mg te bêre

- Bêre by of onder 25 °C.
- Beskerm teen lig en humiditeit.
- Hou in die oorspronklike houer tot nodig vir gebruik.
- HOU 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 of rioolstelsels (bv. toilette) wegdoen nie.

6. Inhoud van die pak en ander inligting
Wat Essentiale® Extreme 300 mg 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® Extreme 300 mglyk en inhoud van die pak:
Essentiale® Extreme 300 mg: 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.

Verpakkingsgroottes: 5, 6, 10, 12, 20, 24, 50, 56, 100, 250 en 600 kapsules.
Nie al die verpakkingsgroottes word bemark nie.

Houer van die Registrasiesertifikaat:
Opella Healthcare South Africa (Edms.) Bpk.
4de Vloer, Gebou I, Hertford Office Park,
Bekkerweg 90, Midrand, 1652

Hierdie inligtingsblad is laas hersien:
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Registrasienommer
N/A