

## Packaging information: information for users

### Essentiale 300 mg hard capsules Phospholipid Essentiale

Please read this leaflet carefully before taking this medicine as it contains important information for you.

Always take this medicine exactly as described in the package leaflet or as directed by your doctor or pharmacist.

- Keep the leaflet in case you need to read it again.
- Ask your pharmacist if you need further information or advice.
- If you experience any of the side effects, tell your doctor or pharmacist. Do the same for any side effects not listed in this leaflet. See section 4.
- If you do not feel better within 14 days or if you feel worse, you must consult your doctor.

What you will find in this leaflet

1. What Essentiale is and what it is used for
2. What you need to pay attention to before taking Essentiale
3. How to take Essentiale
4. Possible side effects
5. How to store Essentiale
6. Package contents and other information

#### **1. What is Essentiale and what is it used for**

Essentiale contains so-called essential (basic) phospholipids, which are part of cell membranes. In liver diseases in which the metabolism in the liver cells is disturbed, the phospholipids thus administered are preferentially used by the liver cells and incorporated into their cell membrane.

The preparation promotes the following processes:

- Normalization of disturbed functions and enzymatic activities of the liver cell.
- Release of energy reserves in the liver tissue.
- Acceleration and promotion of liver cell regeneration.
- Correction of the balance of blood fats.
- Stabilization of bile.

Essentiale is used to improve subjective discomfort in liver inflammation (hepatitis) and in liver diseases caused by toxic-metabolic liver damage (liver damage accompanying liver disease or caused by drugs, alcohol, chemicals, poisoning after ingestion of mushrooms). These difficulties include, for example, loss of appetite and/or a feeling of pressure in the right epigastrium.

Adolescents aged 12 years and over (weighing approximately 43 kg or more) and adults can take the product.

#### **2. What you should pay attention to before taking Essentiale**

Do not take Essentiale:

- If you are allergic to the medicine, soya, peanuts or any of the other ingredients listed in section 6.1).

Warnings and precautions

- Treatment with Essentiale cannot prevent liver damage due to the use of harmful substances (e.g. alcohol).
- If improvement in subjective signs of the condition is observed during treatment, supportive treatment with this product is warranted. If symptoms worsen or other unclear symptoms appear, consult a physician.
- The soybean oil contained in the product may cause a severe allergic reaction in sensitive individuals.

Children and adolescents

Due to insufficient data, Essentiale should not be used by children under 12 years of age.

Other medicinal products and Essentiale

Interactions between Essentiale and medicines that reduce blood clotting (called anticoagulants) cannot be ruled out. For this reason, the dose of the anticoagulant may need to be adjusted. Tell your doctor or pharmacist about any medicines you are taking, have recently taken or may be taking.

Pregnancy, breastfeeding and fertility

Taking this medicine during pregnancy and while breastfeeding is not recommended. Insufficient data are available. If you are pregnant or breastfeeding, think you may be pregnant, or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Driving and operating machinery

This medicine does not affect activities requiring increased attention, coordination of movements or rapid decision making (e.g. driving, operating machinery, working at heights, etc.).

Essentiale contains soybean oil and ethanol (alcohol)

This medicine contains soybean oil. If you are allergic to peanuts or soy, do not take this medicine.

This medicine contains a small amount of alcohol, less than 100 mg per dose.

#### **3. How to take Essentiale**

Always take this medicine exactly as described in the package leaflet or as directed by your doctor or pharmacist. If you are unsure, consult your doctor or pharmacist.

Unless otherwise recommended by your doctor, adults and adolescents 12 years of age and older usually take 2 hard capsules 3 times a day (equivalent to 1800 mg of soy phospholipids per day).

The capsules are swallowed whole with plenty of liquid, preferably with meals.

There is no time limit on the duration of administration, but do not take the product for more than 4 weeks without consulting your doctor.

If your symptoms do not improve or worsen within 7 days, or if other unclear symptoms appear, consult your doctor for further advice.

If you have forgotten to take Essentiale

Do not double the next dose to make up for a missed dose.

If you have taken more Essentiale than you should have taken

Consult your doctor if you overdose, or if your child accidentally ingests more capsules.

If you have any other questions about taking this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine may have side effects, but these may not occur in everyone.

The following side effects have been reported:

Unknown (frequency cannot be determined from available data):

- Stomach upset,
- diarrhoea and soft stools,
- allergic reactions such as rash and urticaria,
- Itching.

Reports of adverse reactions

If you experience any of the side effects, tell your doctor. Do the same for any side effects not listed in this leaflet. You can also report side effects directly to:

State Institute for Drug Control

Šrobárova 48 100 41 Prague 10 website: [www.sukl.cz/nahlasit-nezadouci-ucinek](http://www.sukl.cz/nahlasit-nezadouci-ucinek)

By reporting adverse reactions you can help to obtain more information about the safety of this product.

#### **5. How to store Essentiale**

Keep out of sight and reach of children.

Store at temperatures up to 25 °C in the original inner container to protect the product from moisture. Do not use this product after the expiry date indicated on the box and blister after the abbreviation EXP. The expiry date refers to the last day of the month indicated.

#### **6. Contents of the package and other information**

What Essentiale contains

- The active substance is Phospholipid Essentiale (essential phospholipids) 300 mg in one capsule.

- The excipients in the capsule filling are:

purified soybean oil, solidified fat, hydrogenated castor oil, anhydrous ethanol, methoxyacetophenone, ethylvanillin

- The excipients in the capsule are:

Gelatin, black iron oxide (E 172), yellow iron oxide (E 172), titanium dioxide (E 171), red iron oxide (E 172), purified water.

What does Essentiale look like and what does this pack contain

Essentiale are oval khaki coloured capsules with a honey coloured substance inside.

Packaging description: Al/PVC/ PVDC blister with 10 hard capsules, box. Pack size: 50 or 100 hard capsules per pack.

All pack sizes may not be available on the market.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

Opella Healthcare Czech s.r.o., Evropská 846/176a, 160 00 Prague 6, Czech Republic \

Manufacturer

A. Nattermann & Cie. GmbH, Nattermannallee 1, 50829 Cologne, Germany

This package leaflet was last revised:

13. 4. 2021

## Essentiale 300 mg 硬膠囊 Phospholipid Essentiale

在服用此藥之前，請仔細閱讀本說明書，因為它包含了對您的重要資訊。

一定要嚴格按照包裝上的說明或醫生或藥劑師的指示服用此藥。

- 保存好傳單，以防你需要再次閱讀。
- 如果您需要進一步的資訊或建議，請諮詢您的藥劑師。
- 如果你遇到任何副作用，請告訴你的醫生或藥劑師。對本手冊中未列出的任何副作用也要這樣做。見第 4 節。
- 如果你在 14 天內沒有感覺到好轉，或者感覺更糟，你必須諮詢你的醫生。

你將在本手冊中看到的內容

1. 什麼是 **Essentiale** 以及它的用途
2. 服用 **Essentiale** 前需要注意的事項
3. 如何服用 **Essentiale**
4. 可能的副作用
5. 如何存儲 **Essentiale**
6. 包裝內容和其他資訊

### 1. 什麼是 **Essentiale**，它的用途是什麼

必需品含有所謂的必需（基本）磷脂，是細胞膜的一部分。在肝細胞代謝紊亂的肝臟疾病中，這樣施用的磷脂會優先被肝細胞使用並納入其細胞膜。

該準備工作促進了以下過程。

- 紊亂的功能和肝細胞的酶活性的正常化。
- 釋放肝臟組織中的能量儲備。
- 加速和促進肝細胞的再生。
- 糾正血脂的平衡。
- 穩定膽汁。

**Essentiale** 用於改善肝臟炎症（肝炎）和中毒性代謝性肝損傷（伴隨肝病的肝損傷或由藥物、酒精、化學品、攝入蘑菇後中毒引起的肝臟疾病）的主觀不適。這些困難包括，例如，食欲不振和/或右上腹有壓迫感。

12 歲以上的青少年（體重約 43 公斤或以上）和成年人可以服用本品。

### 2. 服用 **Essentiale** 前應注意的事項

不要服用 **Essentiale**。

- 如果您對藥物、大豆、花生或第 6.1 節中所列的任何其他成分過敏）。

警告和預防措施

- 使用 **Essentiale** 治療不能防止由於使用有害物質（如酒精）造成的肝臟損傷。
- 如果在治療過程中觀察到病情的主觀症狀有所改善，則應使用本品進行支持性治療。如果症狀惡化或出現其他不清楚的症狀，請諮詢醫生。
- 本品所含的大豆油可能會對敏感人士造成嚴重的過敏反應。

兒童和青少年

由於資料不足，12 歲以下的兒童不應使用 **Essentiale**。

其他藥用產品和 **Essentiale**

不能排除 **Essentiale** 與減少血液凝固的藥物（稱為抗凝血劑）之間的相互作用。由於這個原因，可能需要調整抗凝血劑的劑量。告訴你的醫生或藥劑師你正在服用、最近服用或可能服用的任何藥物。

懷孕、母乳餵養和生育能力

不建議在懷孕期間和哺乳期服用此藥。沒有足夠的資料。如果您正在懷孕或哺乳，認為自己可能懷孕，或計畫懷孕，請在服用此藥前諮詢您的醫生或藥劑師。

駕駛和操作機器

這種藥不影響需要提高注意力、協調動作或快速決策的活動（如駕駛、操作機器、高空作業等）。

**Essentiale** 含有大豆油和乙醇（酒精）。

此藥含有大豆油。如果你對花生或大豆過敏，請不要服用此藥。

此藥含有少量的酒精，每劑少於 100 毫克。

### 3. 如何服用 **Essentiale**

一定要嚴格按照包裝上的說明或醫生或藥劑師的指示服用此藥。如果你不確定，請諮詢你的醫生或藥劑師。除非醫生另有建議，成人和 12 歲以上的青少年通常每天 3 次服用 2 粒硬膠囊（相當於每天 1800 毫克的大豆磷脂）。

膠囊與大量液體一起整粒吞服，最好是在吃飯時吞服。

服用時間沒有限制，但在沒有諮詢醫生的情況下，不要服用本品超過 4 周。

如果你的症狀在 7 天內沒有改善或惡化，或出現其他不清楚的症狀，請諮詢醫生以獲得進一步建議。

如果你忘記服用 **Essentiale**

不要為了彌補漏服的劑量而將下一次的劑量加倍。

如果你服用的 **Essentiale** 超過你應該服用的數量

如果用藥過量，或孩子不小心吃了更多的膠囊，請諮詢醫生。

如果您對服用此藥有任何其他問題，請諮詢您的醫生或藥劑師。

#### **4. 可能的副作用**

像所有的藥物一樣，這種藥物可能有副作用，但這些副作用不一定發生在每個人身上。

已有以下副作用的報告。

不明（根據現有資料無法確定頻率）。

- 胃部不適。

- 腹瀉和軟便。

- 過敏反應，如皮疹和蕁麻疹。

- 瘙癢。

不良反應的報告

如果你遇到任何副作用，請告訴你的醫生。對本手冊中未列出的任何副作用也要這樣做。你也可以直接報告副作用。

國家藥物控制研究所

Šrobárova 48 100 41 Prague 10 網站: [www.sukl.cz/nahlasit-nezadouci-ucinek](http://www.sukl.cz/nahlasit-nezadouci-ucinek)

通過報告不良反應，你可以說明獲得更多關於本產品安全性的資訊。

#### **5. 如何存儲 Essentiale**

不要讓兒童看到和接觸到。

在溫度不超過 25°C 的情況下，儲存在原內包裝中，以防止產品受潮。請勿在包裝盒和泡罩上的縮寫 EXP 後的有效期內使用本品。有效期是指所標明的月份的最後一天。

#### **6. 包裝的內容和其他資訊**

**Essentiale** 包含哪些內容

- 活性物質是 **Phospholipid Essentiale**（基本磷脂）300 毫克，一粒膠囊。

- 膠囊填充物中的賦形劑是。

純化大豆油，固化脂肪，氫化蓖麻油，無水乙醇，甲氧基苯乙酮，乙基香蘭素

- 膠囊中的賦形劑是。

明膠，黑色氧化鐵（E 172），黃色氧化鐵（E 172），二氧化鈦（E 171），紅色氧化鐵（E 172），純淨水。

**Essentiale** 是什麼樣子的，這包東西包含什麼？

**Essentiale** 是橢圓形的卡其色膠囊，裡面是蜂蜜色的物質。

包裝描述。鋁/PVC/PVDC 泡殼，含 10 個硬膠囊，盒。包裝規格：每包 50 或 100 粒硬膠囊。市場上可能沒有所有的包裝尺寸。

上市許可持有人和製造商

行銷授權持有人

Opella Healthcare Czech s.r.o., Evropská 846/176a, 160 00 Prague 6, Czech Republic

製造商

A. Nattermann & Cie. GmbH, Nattermannallee 1, 50829 Cologne, Germany

本包裝傳單的最後一次修訂。

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