

Package leaflet: information for the patient  
Essentiale Forte, 300 mg, capsules  
Phospholipid Essentiale

Read the leaflet carefully before taking this medicine, as it contains important information for you.

Always take this medicine exactly as described in this leaflet or as prescribed by your doctor, pharmacist or nurse.

- Keep this leaflet so you can read it again if you need to.

- If you need advice or further information, ask your pharmacist.

- If you experience any side effects, including any possible side effects not listed in this leaflet, tell your doctor, pharmacist or nurse. See section 4.

- If there is no improvement after a few days, or if you feel worse, contact your doctor.  
contact your doctor.

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

Essentiale Forte is a herbal medicine used in liver diseases.

It contains essential phospholipids (Phospholipid Essentiale), which are glycerol esters of cholinophosphoric acid and unsaturated fatty acids: linoleic, linolenic and oleic. These phospholipids cannot be synthesised in the body due to their polyunsaturated fatty acid content in the side chains.

The phospholipids contained in Essentiale Forte, after entering the liver, are built into the membranes of liver cells. This results in supplementation of the existing losses caused by the disease process and faster regeneration of the damaged liver cells.

Phospholipids are essential for differentiation and proliferation of liver cells. They inhibit fibrotic processes in the liver by reducing collagen production and increasing the activity of the enzyme collagenase which breaks it down.

Phospholipids, which are built into the membranes of liver cells, reduce the sensitivity of these cells to immune system factors that can damage them.

Phospholipids are secreted into bile, where they reduce the cholesterol/phospholipid ratio and increase the solubility of cholesterol - thanks to the emulsifying properties of essential phospholipids, this is important in the prevention of cholelithiasis.

Along with bile acids, phospholipids play an important role in the digestion of fats and the absorption of vitamins dissolved in them.

Moreover, polyunsaturated fatty acids contained in phospholipids reduce cholesterol concentration and normalise serum lipoprotein levels - showing beneficial anti-atherosclerotic effects. They also increase the transport of cholesterol from extrahepatic tissues to the liver and activate lipolytic enzymes. Polyunsaturated fatty acids improve blood flow in vessels by decreasing adhesion of platelets and increasing elasticity of red blood cells.

Indications for use

Reduces subjective complaints of the patient such as: lack of appetite, pressure sensation in the right epigastrium caused by liver damage due to improper diet, toxic substances or in the course of hepatitis.

If there is no improvement after a few days, if the patient feels worse, if the symptoms worsen, or if other non-specific symptoms occur, seek medical advice.

### **2. Information important before using Essentiale Forte**

When not to use Essentiale Forte

- If the patient is allergic to the active substance, soya, peanuts or any of the other components of this medicine (listed in section 6).

Warnings and precautions

Discuss with your doctor or pharmacist before taking Essentiale Forte.

Children and adolescents

There is insufficient data on the use of Essentiale Forte in children under 12 years of age. Therefore, Essentiale Forte should not be used in children under 12 years of age.

Essentiale Forte and other medicines

Tell your doctor or pharmacist about all the medicines you are currently or recently taking and any medicines you are planning to take.

Consult your doctor before taking the drug at the same time with anticoagulants.

Essentiale Forte with food and drink

The capsules should be taken during meals, without chewing (wash down with e.g. a glass of water).

Pregnancy and breast feeding

If you are pregnant or breast-feeding, or think you may be pregnant, or are planning to have a baby, you should consult your doctor or pharmacist before taking this medicine.

Soybean seeds are often a component of food, so far no harmful effect on pregnancy has been observed during their use.

However, insufficient studies have been performed. Therefore, the use of the drug during pregnancy and breast feeding is not recommended.

Driving of vehicles and operation of moving mechanisms

Essentiale Forte has no influence on the ability to drive vehicles and operate moving mechanisms.

Essentiale Forte contains soya oil.

Because of soya oil content, the drug may cause severe allergic reactions.

Do not apply in case of known hypersensitivity to peanuts or soya. The drug contains small amounts of ethanol (alcohol), less than 100 mg per capsule.

### **3. How to use Essentiale Forte**

Always take this medicine exactly as described in the patient information leaflet or as prescribed by your doctor, pharmacist or nurse. If in doubt, ask your doctor, pharmacist or nurse.

Adults and children over 12 years of age: 2 capsules 3 times daily.

Use in children and adolescents

There are no sufficient data on the use of Essentiale Forte in children below 12 years of age. Therefore, Essentiale Forte should not be used in children below 12 years of age.

The capsules should be taken during meals, without chewing (wash down, e.g. with a glass of water). The duration of therapy is not limited.

Taking higher than recommended dose of Essentiale Forte

So far, no cases of Essentiale Forte overdose have been described.

In case of taking higher than recommended dose of Essentiale Forte, undesired effects described below may intensify.

### **4. Possible undesired effects**

As every drug, this medicine may cause undesired effects, although they will not occur in every patient.

Frequency unknown (frequency cannot be established from the available data): allergic reaction such as erythema, rash, urticaria, pruritus, gastrointestinal disorders such as nausea, loose stools, diarrhoea, abdominal discomfort may occur.

Reporting of side effects

If you notice any side effects, including any side effects not listed in this leaflet, please tell your doctor or pharmacist. Undesirable effects can be reported directly to the Department for Undesirable Medicinal Product Reactions

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Tel: + 48 22 49 21 301 Fax: + 48 22 49 21 309 e-mail: [ndl@urpl.gov.pl](mailto:ndl@urpl.gov.pl) Adverse reactions can also be reported to the responsible entity.

By reporting side effects, more information on the safety of the medicine can be gathered.

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

Store the drug out of sight and reach of children.

Store at the temperature below 25C, protect from moisture.

Do not use this medicine after expiry date stated on the package. The expiry date refers to the last day of the stated month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer in use. This will help protect the environment.

### **6. package contents and other information**

What does Essentiale Forte contain?

- The active substance of the drug are: soya bean phospholipids containing (3-sn-phosphatidyl)choline, 1 capsule contains 300 mg.

- Excipients: refined soybean oil, hydrogenated castor oil, hydrogenated vegetable glycerides (Witepsol W 35), triglycerides of higher fatty acids (Witepsol S 55), ethanol, ethylwanilin, p-methoxyacetophenone,  $\alpha$ -tocopherol.

Cover: gelatine, yellow iron oxide (E 172), black iron oxide (E 172), red iron oxide (E 172), titanium dioxide (E 171), sodium lauryl sulphate, purified water.

What Essentiale Forte looks like and what it contains in the package

A yellow to brown paste of honey consistency in a green, opaque, oblong capsule.

A package contains 50 or 100 capsules.

Marketing authorisation holder and manufacturer

Podmiot odpowiedzialny Sanofi-Aventis Sp. z o.o.

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Manufacturer

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D-50829 Cologne, Germany

Sanofi-Aventis Sp. z o.o. w Warszawie

Oddział w Rzeszowie

Zakład Produkcji i Dystrybucji Leków ul. Lubelska 52 35-233 Rzeszów

For more detailed information, contact

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包裝傳單：給病人的資訊  
**Essentiale Forte, 300 mg, 膠囊**  
**Phospholipid Essentiale**

在服用此藥之前，請仔細閱讀本說明書，因為它包含了對您重要的資訊。

一定要嚴格按照本手冊的描述或醫生、藥劑師或護士的處方服用此藥。

- 請保留這份傳單，以便你在需要時可以再次閱讀。

- 如果你需要建議或更多資訊，請諮詢你的藥劑師。

- 如果您遇到任何副作用，包括本手冊中未列出的任何可能的副作用，請告訴您的醫生、藥劑師或護士。見第 4 節。

- 如果幾天後沒有改善，或感覺更糟，請聯繫醫生。

聯繫你的醫生。

傳單內容

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**1. Essentiale Forte 是什麼以及它的用途**

**Essentiale Forte** 是一種用於治療肝病的草藥。

它含有必需的磷脂（**Phospholipid Essentiale**），是膽鹼磷酸的甘油酯和不飽和脂肪酸：亞油酸、亞麻酸和油酸。這些磷脂由於其側鏈中含有多不飽和脂肪酸，所以不能在體內合成。

**Essentiale Forte** 所含的磷脂在進入肝臟後，被構建在肝細胞的膜上。這導致補充由疾病過程造成的現有損失，並加快受損肝細胞的再生。

磷脂是肝細胞分化和增殖的必要條件。它們通過減少膠原蛋白的產生和增加分解膠原蛋白的酶的活性來抑制肝臟中的纖維化。構建在肝細胞膜上的磷脂，降低了這些細胞對可能損害它們的免疫系統因素的敏感性。

磷脂被分泌到膽汁中，在那裡它們降低膽固醇/磷脂的比例並增加膽固醇的溶解度--由於基本磷脂的乳化特性，這對預防膽石症很重要。

與膽汁酸一起，磷脂在消化脂肪和吸收溶於脂肪的維生素方面發揮著重要作用。

此外，磷脂中含有的多不飽和脂肪酸可降低膽固醇濃度，使血清脂蛋白水準正常化--顯示出有益的抗動脈粥樣硬化作用。它們還能增加膽固醇從肝外組織向肝臟的運輸，並啟動脂肪分解酶。多不飽和脂肪酸通過減少血小板的粘附和增加紅血球的彈性來改善血管中的血流。

使用適應症

減少病人的主觀抱怨，如：食欲不振，因飲食不當、有毒物質或肝炎過程中造成的肝臟損傷而導致的右上腹壓迫感。

如果幾天後沒有改善，如果病人感覺更糟，如果症狀惡化，或者出現其他非特異性症狀，請尋求醫生建議。

2. 使用 **Essentiale Forte** 前的重要資訊

什麼時候不能使用 **Essentiale Forte**

- 如果病人對活性物質、大豆、花生或本藥的任何其他成分（列於第 6 節）過敏。

警告和預防措施

在服用 **Essentiale Forte** 之前，請與您的醫生或藥劑師進行討論。

兒童和青少年

在 12 歲以下兒童中使用 **Essentiale Forte** 的資料不足。因此，**Essentiale Forte** 不應該用於 12 歲以下的兒童。

**Essentiale Forte** 和其他藥物

告訴你的醫生或藥劑師你目前或最近正在服用的所有藥物以及你計畫服用的任何藥物。

在與抗凝劑同時服用該藥前請諮詢醫生。

**Essentiale Forte** 與食品和飲料

膠囊應在進餐時服用，不需咀嚼（如用一杯水沖服）。

懷孕和母乳餵養

如果您正在懷孕或哺乳，或認為自己可能懷孕，或打算生孩子，在服用此藥前應諮詢醫生或藥劑師。

大豆種子通常是食品的組成部分，到目前為止，在使用過程中還沒有發現對懷孕的有害影響。

然而，還沒有進行充分的研究。因此，不建議在懷孕和哺乳期使用該藥。

駕駛車輛和操作移動機構

**Essentiale Forte** 對駕駛車輛和操作移動機構的能力沒有影響。

**Essentiale Forte** 含有大豆油。

由於含有大豆油，該藥可能引起嚴重的過敏反應。

在已知對花生或大豆過敏的情況下，請勿使用。該藥物含有少量的乙醇（酒精），每粒少於 100 毫克。

3. 如何使用 **Essentiale Forte**

一定要嚴格按照患者資訊手冊中的描述或醫生、藥劑師或護士的處方服用此藥。如果有疑問，請詢問您的醫生、藥劑師或護士。

成人和 12 歲以上的兒童。每日 3 次，每次 2 粒。

在兒童和青少年中使用

沒有足夠的資料表明 **Essentiale Forte** 在 12 歲以下兒童中的應用。因此，**Essentiale Forte** 不應在 12 歲以下的兒童中使用。

膠囊應在進餐時服用，無需咀嚼（用一杯水沖洗）。治療的時間不受限制。

服用高於建議劑量的 **Essentiale Forte**

到目前為止，還沒有描述 **Essentiale Forte** 過量的案例。

如果服用超過建議劑量的 **Essentiale Forte**，以下描述的不良反應可能會加劇。

#### 4. 可能的不良影響

與每一種藥物一樣，這種藥物可能會引起不良反應，儘管不是每個病人都會出現這種情況。

頻率未知（根據現有資料無法確定頻率）：可能出現過敏反應，如紅斑、皮疹、蕁麻疹、瘙癢，胃腸道紊亂，如噁心、稀便、腹瀉、腹部不適。

副作用的報告

如果您發現任何副作用，包括本手冊中未列出的任何副作用，請告訴您的醫生或藥劑師。不良反應可直接報告給不良藥品反應部

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電話：+ 48 22 49 21 301 傳真：+ 48 22 49 21 309 電子郵件：ndl@urpl.gov.pl 不良反應也可以報告給負責的實體。

通過報告副作用，可以收集更多關於藥品安全性的資訊。

#### 5. 如何儲存 **Essentiale Forte**

將藥物存放在兒童看不到和夠不著的地方。

儲存在 25°C 以下，防止受潮。

請勿在包裝上注明的有效期後使用此藥。到期日是指所述月份的最後一天。

藥品不應通過廢水或生活垃圾進行處理。請向您的藥劑師詢問如何處理不再使用的藥品。這將有助於保護環境。

減少病人的主觀抱怨，如：食欲不振，因飲食不當、有毒物質或肝炎過程中造成的肝臟損傷而導致的右上腹壓迫感。

如果幾天後沒有改善，如果病人感覺更糟，如果症狀惡化，或者出現其他非特異性症狀，請尋求醫生建議。

#### 6. 包裝內容和其他資訊

**Essentiale Forte** 含有什麼成分？

- 該藥物的活性物質是：含有（3-sn-磷脂醯）膽鹼的大豆磷脂。

1 粒膠囊含 300 毫克。

- 輔料：精製大豆油，氫化蓖麻油，氫化植物甘油酯（Witepsol W 35），高級脂肪酸甘油三酯（Witepsol S 55），乙醇，乙二胺，對甲氧基苯乙酮， $\alpha$ -生育酚。

覆蓋物：明膠，黃色氧化鐵（E 172），黑色氧化鐵（E 172），紅色氧化鐵（E 172），二氧化鈦（E 171），十二烷基硫酸鈉，純淨水。

**Essentiale Forte** 的外觀和包裝中的內容

綠色不透明的長方形膠囊中含有黃色至棕色的蜂蜜糊狀物。

一個包裝包含 50 或 100 粒膠囊。

上市許可持有人和製造商

**Podmiot odpowiedzialny Sanofi-Aventis Sp. z o.o.**

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更詳細的資訊，請聯繫

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本傳單的最後修訂日期：2019 年 2 月