

PACKAGE LEAFLET: INFORMATION FOR THE USER

Essentiale Forte N

300 mg hard capsule

SOYBEAN PHOSPHOLIPIDS

FOR USE IN CHILDREN, ADOLESCENTS AND ADULTS.

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What ESSENTIALE FORTE N is and what it is used for
2. Before you take ESSENTIALE FORTE N
3. How to take use ESSENTIALE FORTE N
4. Possible side effects
5. How to store ESSENTIALE FORTE N
6. Further information

1. WHAT ESSENTIALE FORTE N IS AND WHAT IT IS USED FOR

Essentiale is an herbal medicine for liver diseases.

Essentiale Forte N 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 substances harmful to the liver as well as poor diet (toxic effects of certain foods) and in those with chronic liver inflammation (hepatitis).

2. BEFORE YOU TAKE ESSENTIALE FORTE N

Do not take ESSENTIALE FORTE N

- If you are hypersensitive (allergic) to soybeans or to any of the other ingredients in this medicine (see section 6).

This medicine contains soya oil. In rare cases, it may therefore cause severe allergic reactions.

Take special care with ESSENTIALE FORTE N

If your symptoms worsen or if other unclear symptoms appear. If this occurs, you should consult a doctor.

Use of this medicine does not replace avoidance of substances that damage the liver (e.g. alcohol).

If you have chronic liver inflammation (hepatitis), supportive treatment with this medicine is only justified if you notice an improvement in your symptoms.

Children

Sufficient studies are not available concerning use of Essentiale Forte N in children. Therefore, it should not be used in children under 12 years of age.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

An interaction between Essentiale Forte N and medicines that inhibit coagulation of the blood cannot be ruled out. It may therefore be necessary to adjust the dosage of this medicine. If you are taking Essentiale Forte N at the same time as a medicine that inhibits coagulation of the blood, you should inform your doctor.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Widespread use of soybeans as a foodstuff has yielded no evidence of risks in pregnancy and breast-feeding. Sufficient studies are not available. Therefore, use of this medicine during pregnancy and breast-feeding is not recommended.

Driving and using machines

No specific precautions are required.

3. HOW TO TAKE ESSENTIALE FORTE N

Always take Essentiale Forte N exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

Unless your doctor prescribes otherwise, the usual dosage is as follows:

| Age (bodyweight) | Single dose | Total daily dose |
|--|---|---|
| Children of 12 years and older (about 43 kg) Adolescents and adults | 2 Hard capsule (600 mg phospholipids from soya beans) | 2 hard capsule 3 times daily (1800 mg of soybean phospholipids) |

Essentiale Forte N capsules should be swallowed whole with sufficient liquid (preferably a [200 ml] glass of water) during meals.

In principle, there is no time limit for how long you can take this medicine. Please consider the information in Section 2.

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

If you take more ESSENTIALE FORTE N than you should

No symptoms of overdose or poisoning are known for Essentiale capsule 300 mg.

It is possible that the side effects listed below could occur with greater intensity. If this happens, please inform a doctor. He or she can decide whether any measures need to be taken.

If you forget to take ESSENTIALE FORTE N

If you take too few Essentiale capsule 300 mg or forget to take a dose, do not take a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency of side effects is based on the following categories:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

Significant signs or side effects that you should be aware of and measures to be taken if you have a side effect:

Uncommonly, digestive disorders such as stomach disorders, soft stools or diarrhea may occur.

Very rare, allergic reactions such as skin rash or hives may occur. It can occur pruritus (itching) frequency is not known.

If you notice that you have any of the side effects listed above, particularly allergic reactions, stop taking Essentiale capsule 300 mg and inform your doctor. He or she can determine the severity of the side effect and decide whether any measures need to be taken.

Reporting of side effects

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ESSENTIALE FORTE N

Keep out of the reach and sight of children.

Store this medicine out of the reach of children. This medicine should no longer be used after the expiry date printed on the container and box after "EXP". The expiry date is the last day of the month indicated.

Storage conditions:

Do not store above 25 °C. Store in the original package in order to protect from moisture.

6. FURTHER INFORMATION

What ESSENTIALE FORTE N contains

The active substance is: enriched deoiled soybean phospholipids 300 mg.

Capsule filling

- hard fat;
- soybean oil, refined;

- alpha-tocopherol;
- castor oil, hydrogenated;
- ethanol 96%;
- ethyl vanillin;
- 4-methoxyacetophenone.

Capsule shell

- gelatin;
- Purified water:
- titanium dioxide (E171);
- iron (III) oxide, yellow (E 172);
- iron (III) oxide, black (E172);
- iron (III) oxide, red (E 172):
- Sodium lauryl sulfate.

What ESSENTIALE FORTE N looks like and contents of the pack
Original package contains 30 hard capsules.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Sanofi-Aventis Groupe
174 Avenue de France
75013 Paris
France

Manufacturer of the medicinal product

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