

ESSENTIALE[®] FORTE N CAPSULE

Phospholipid from soybeans (300mg)

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What Essentiale Forte N is used for

Essentiale Forte N is used as nutritional support in the management of damaged liver (due to chronic liver disease, liver cirrhosis, fatty liver and intoxication by substances that can cause liver damage)

How Essentiale Forte N works

- Essentiale Forte N contains essential phospholipids (from soya-bean) for liver protection and helps maintain normal function of the liver.
- A daily intake of Essentiale Forte N removes fat deposits in the liver, ensures the improvement in the liver's detoxification function and supports the restoration of the liver's cellular structure.

Before you use Essentiale Forte N

-When you must not use it

Do not take Essentiale Forte N if:

- if you are hypersensitive (allergic) to soybean phospholipids, soya protein, peanut or to any of the other ingredients in this medicine listed in section 8.

This medicine contains soya oil, which may cause severe allergic reactions in rare cases.

-Before you start to use it

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

The 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 therapy with this medicine is only justified if you

notice an improvement of your symptoms.

-Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken other medicines, including those 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. Patients who are taking Essentiale Forte N at the same time as such medicines inhibiting the coagulation of the blood, should inform their doctor.

How to use Essentiale Forte N

You should check with your doctor or pharmacist if you are not sure.

- Swallow your capsule orally with a glass of water.

-How much to use

- The starting dose is 3 times daily 2 capsules (600mg phospholipids from soya-beans)
- The maintenance dose is 3 times daily 1 capsule (300mg phospholipids from soya-beans)
- Do not take more than 6 capsules a day (1800mg phospholipids from soya-beans)

Essentiale Forte N is not recommended for use in children and adolescents below 12 years of age.

-When to use it

Take Essentiale Forte N at about the same time each day.

-How long to use it

Continue taking this product for as long as your doctor tells you.

-If you forget to use it

- If you forget a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten capsule.

-If you use too much (overdose)

No symptoms of overdose or poisoning are known for Essentiale Forte N.

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

While you are using it

-Things you must do

Do not take Essentiale Forte N if:

- You are pregnant or think you may be pregnant.
- You are breast-feeding.

-Things you must not do

- Do not give this product to anyone else, even if they have the same condition as you.
- Do not use this product to treat any other complaints unless your doctor tells you to.
- Do not stop taking Essentiale Forte N, or change the dosage, without checking with your doctor.

-Things to be careful of

Driving and using machines: Essentiale Forte N has no effect on the ability to drive and to use machines.

Side Effect

Like all medicines, Essentiale Forte N can cause side effects, although not everyone gets them.

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

Not known (frequency cannot be estimated from the available data):

- Increased blood pressure
- Palpitations
- Dizziness
- Stomach disorders such as nausea, vomiting, soft stools and/or diarrhea.
- Allergic reactions e.g. skin rash and hives, itching (pruritus).

If you notice that you have any of the side effects listed above, particularly hypersensitivity reactions, stop taking Essentiale Forte N and inform your doctor. He or she can determine the severity of the side effect and decide

whether any measures need to be taken.

If you get any side effects, talk to your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

B-11-01, The Ascent, Paradigm No. 1,
Jalan SS7/26A, Kelana Jaya 47301,
Petaling Jaya, Selangor Darul Ehsan,
Malaysia.

Date of revision

10/07/2023 (based on SmPC dated 09 2022)

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Storage and Disposal of Essentiale Forte N

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

-Storage

- Keep out of the reach and sight of children.
- Do not use Essentiale Forte N after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Store in the original container in order to protect from humidity.
- Do not store above 30°C.

-Disposal

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

Product Description

-What it looks like

Essentiale Forte N is in khaki, opaque, oblong hard capsule.

-Ingredients:

Active ingredients: phospholipids from soya beans 300 mg.

Inactive ingredients:

ethanol 96%, hard fat, soya-bean oil, hydrogenated castor oil, ethyl vanillin, 1-(4-methoxyphenyl) ethanone, alpha-tocopherol, gelatin, colouring agents E 171, 172, purified water.

-MAL Numbers:

MAL06071088X

Manufacturer

A. Nattermann & Cie GmbH
Nattermannallee 1
D-50829, Koln, Germany.

Product Registration Holder

DKSH Malaysia Sdn Bhd