Phospholipids

Essentiale ® Forte P
300 mg Hard Gelatin Capsule
Hepatoprotector

SANOFI

Formulation
Each hard gelatin capsule contains:
De-oiled enriched phospholipids from soya-beans ..... 300 mg
For the list of excipients see section on Excipients

Pharmaceutical form
Hard gelatin capsule for oral use.

CLINICAL PARTICULARS
Indications
Nutritional support in the management of damaged liver (due to chronic liver disease, liver cirrhosis, fatty liver & intoxication by hepatotoxic substances).

Dosage and Method of Administration

Age and/or body weight	Single dose	Total daily dose
Children from 12 years (approx. 43 kg) Adolescents and adults	2 hard gelatin capsules (600 mg of soya-bean phospholipids)	3 times daily 2 hard gelatin capsules (1800 mg of soya-bean phospho-lipids)

Essentiale Forte P capsule 300 mg is taken unchewed with meals with plenty of liquid (e.g. with a glass of water).
Basically, the duration of the application is not limited.
The patient leaflet mentions that the information given under “precautions and warnings” should be taken into account.

Contraindications
Known hypersensitivity to soya-bean preparations or to any of the excipients.

Special warnings and precautions for use
The leaflet draw the attention of the patient to the following: This drug therapy is not a substitute for the avoidance of the noxious agent causing liver damage (e.g. alcohol).
In chronic hepatitis the adjuvant therapy with soya-bean phospholipids is justified only when improved subjective well-being becomes manifest during therapy.
Consult your doctor when complaints aggravate or when other unclear complaints occur.

Children
As information about the administration in children is insufficient, Essentiale Forte P capsule 300 mg should not be given to children under 12 years of age.
Due to the content in soya-bean oil the medicinal product may provoke severe allergic reactions.

Interactions with other medicinal products and other forms of interaction
An interaction of Essentiale Forte P capsule 300 mg with anticoagulants cannot be excluded. For this reason, dose adjustment of the anticoagulant might be necessary.
The leaflet advises the patient to consult a doctor in the case of simultaneous application.

Pregnancy and lactation
Preparations from soya-beans are largely used in human food and so far no clue has appeared that would suggest any risk during pregnancy. Results from investigation are insufficient. For this reason, the use of Essentiale Forte P capsule 300 mg is not recommended during pregnancy and lactation.

Effects on ability to drive and use machines
Essentiale Forte P capsule 300 mg has no effect on the ability to drive and to use machines.

Undesirable effects
For the evaluation of any adverse effects the following incidences are considered:
very frequent (≥1/10)
frequent (≥1/100 to ≥1/10)
occasional (≥1/1,000 to ≥1/100)
rare (≥ 1/10,000 to ≥ 1/1,000)
very rare (< 1/10,000)

Occasionally the administration of Essentiale Forte P capsule 300 mg may provoke gastrointestinal disorders, such as stomach complaints, soft stool and diarrhoea.

On very rare occasions allergic reactions may occur, such as exanthema and urticaria. The doctor or pharmacist should be informed about any undesirable effect not listed in the leaflet.
The leaflet informs that the administration of Essentiale Forte P capsule 300 mg should be discontinued in the event of one of the above mentioned side effects, especially in hypersensitivity reactions. The patient should consult the doctor who may decide about the severity and any measures that might be necessary.

Overdose
No overdose reaction nor symptom of intoxication has been reported to date with Essentiale Forte P capsule 300 mg.
The leaflet informs that the below listed undesirable effects may be reinforced.
The patient should consult the doctor who may decide about the severity and any measures that might be necessary.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
ATC Code: A05BA

Among the pharmacodynamic properties were reported hepatoprotective effects found in numerous experimental models into acute liver damage, for example induced by ethanol, alcyl alcohol, carbon-tetrachloride, paracetamol and galactosamine. Moreover, in chronic models (ethanol, thioacetamide, organic solvents) was seen also the inhibition of steatosis and fibrosis. As active principles have been suggested accelerated membrane regeneration and stabilization, inhibited lipid peroxidation and inhibited collagen synthesis. Specific investigations into human pharmacodynamics are not available.

Pharmacokinetic properties
Animal experiments into the pharmacokinetics showed that more than 90% of the orally applied soya-bean phospholipids are absorbed in the small intestine. Most of it is split by phospholipase A to 1-acyl-lysophosphatidylcholine. 50% of which is reacylated immediately into polyunsaturated phosphatidylcholine still during the process of absorption in the intestinal mucosa. This polyunsaturated phosphatidylcholine reaches the blood via the lymph pathway and from there - mainly bound to HDL - it passes in particular to the liver.

Tests into human pharmacokinetics were performed a.o. with radioactively labeled dilinoleoyl-phosphatidylcholine (^{3}H and ^{14}C). The choline moiety was ^{3}H-labeled and the linoleic acid had the ^{14}C-label.
The maximum ^{3}H concentration was achieved after 6 to 24 hours and amounted to 19.9% of the dose.
The half-life for the choline component was 66 hours.
The maximum ^{14}C concentration was achieved after 4 to 12 hours and amounted to 27.9% of the dose.
The half-life for this component was 32 hours. In the faeces were found 2% of the ^{3}H and 4.5% of the ^{14}C label, in the urine 6% of the ^{3}H and only minor amount of the ^{14}C label. These results show that both isotopes are absorbed to over 90% in the intestine.

PHARMACEUTICAL PARTICULARS
List of excipients: Ethanol 96%, hard fat, soya-bean oil (Ph. Eur.), hydrogenated castor oil, ethyl vanillin, 1-(4-methoxyphenyl) ethanone, alpha-tocopherol, gelatin, colouring agents E 171, 172, sodium laurylsulfate, purified water.

Incompatibilities: Not applicable.

Storage: Store at temperatures not exceeding 30°C. Store in original package. Protect from moisture.

Availability: Alu/PVC/PE/PVDC Blister Pack x 10's (Box of 50's)

Caution: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescripition.

Reporting of Side Effects or any Suspected Adverse Event
For suspected adverse drug reaction, report to the FDA: **www.fda.gov.ph**.
If you experience any side effects with the use of this product, you are advised to seek medical attention.
You are also encouraged to report any side effects to Sanofi Philippines Pharmacovigilance Unit via **PV.Philippines@sanofi.com**.
By reporting side effects, you can help provide more information on the safety of this product.

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