Essentiale® MAX 600mg

Opella.

1. Name of the medicinal product
Essentiale MAX 600mg capsule

2. Qualitative and quantitative composition
One hard capsule contains 600 mg of deoiled enriched soybean phospholipids.
Contain of ethanol approx. 2% as solvent.
For the full list of excipients, see section 6.1.

3. Pharmaceutical form & Description
A mahogany, opaque, elongated hard capsule for oral use.

4. Clinical particulars
4.1 Therapeutic indications
Nutritional support in the management of damaged liver (due to chronic liver disease, liver cirrhosis, fatty liver & intoxication by hepatotoxic substances).

4.2 Posology, method and duration of administration
For Adult and 18 year and above: Take 1 hard capsule 3 times daily (Total daily dose: 1800 mg of soybean phospholipids).
Essentiale MAX 600 mg hard capsules should be swallowed whole with sufficient liquid (preferably a 200 ml glass of water) during meals.
Renal Insufficiency
There is insufficient data for specific dosage recommendations for patients with impaired renal function

4.3 Contraindications
Hypersensitivity to the active substance, soybean proteins, peanut or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
The patient is advised in the package leaflet that this medicinal treatment is not a substitute for avoiding sources that damage the liver (e.g. alcohol).
If you have chronic hepatitis, supportive treatment with soya bean phospholipids is only justified if an improvement in the subjective signs of your condition is observed under treatment. If the symptoms get worse or if other unclear symptoms appear, the patient should consult a doctor.
Contains alcohol (less than 100 mg per single dose).

Children and adolescents aged under 18 years
Sufficient studies are not available concerning use of Essentiale MAX 600 mg hard capsules in children and adolescents. Furthermore, there is no relevant use in these patients due to the indication. Essentiale MAX 600 mg hard capsules should not be applied in children and adolescents under 18 years.

4.5 Interaction with other medicinal products and other forms of interaction
An interaction between Essentiale MAX 600 mg hard capsules and anticoagulants cannot be ruled out. Therefore, it may be necessary to adjust the dose of this medicinal product. The package leaflet contains an advises that patients should inform their doctor if they are using Essentiale Max 600 mg hard capsules at the same time as this type of medicine.

4.6 Fertility, pregnancy and lactation
Pregnancy
There are only limited amount of data from the use of Essentiale MAX 600 mg hard capsules in pregnant women. Animal studies concerning reproduction toxicity are insufficient (see section 5.3). The use of Essentiale MAX 600 mg hard capsules in pregnant women is not recommended.
Breastfeeding
It is not known whether components of soybean phospholipids or their metabolites pass into breast milk. A risk for breast-fed infants cannot be ruled out. Essentiale MAX 600 mg hard capsules should not be taken by breast-feeding women.
Fertility
Preclinical studies in animals have not demonstrated an effect on male or female fertility.

4.7 Effects on ability to drive and use machines
Essentiale MAX 600 mg hard capsules has no influence on the ability to drive and use machines.

4.8 Undesirable effects
The frequency of side effects is based on the following categories:
Very common (≥ 1/10)
Common (≥ 100 to < 1/10)
Uncommon (≥ 1/1 000 to < 1/100)
Rare (≥ 1/10 000 to < 1/1 000)
Very rare (< 1/10 000)
Not known (frequency cannot be estimated from the available data)
Gastrointestinal disorders
Not known: gastrointestinal disorders in form of nausea, vomiting, soft stools and/ or diarrhoea.
Investigations
Not known: Increased blood pressure

Cardiac disorders
Not known : Palpitations
Nervous system disorders
Not known: Dizziness
Skin and subcutaneous tissue disorders
Not known: allergic reactions such as exanthema and urticaria, pruritus.
In rare cases, this medicinal product can cause severe allergic reactions, as it contains soya oil.
Side effects that are not mentioned in the package leaflet should be reported to a doctor or pharmacist.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/ risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9 Overdose
There are no known cases of overdose or intoxication with Essentiale MAX 600 mg hard capsules up to now. In the package leaflet, the patient is advised of the following:" 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 whether any measures need to be taken."

5. Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Liver therapy
ATC Code: A05BA10
The exact mode of action is not known. There are no specific studies available on pharmacodynamics in man

5.2. Pharmacokinetic properties
Pharmacokinetic studies in man were conducted with ^{3}H and ^{14}C radiolabeled dilinoleoylphosphatidylcholine, among other substances. The choline residue was labeled with ^{3}H and the linoleic acid with ^{14}C.
Peak ^{3}H concentrations were reached between 6 and 24 hours and accounted for 19.9% of the dose. The half-life of the choline component was 66 hours.
Peak ^{14}C concentrations were reached between 4 and 12 hours and were 27.9% of the dose. The half-life of this component was 32 hours. 2% of the ^{3}H and 4.5% of the ^{14}C markers were recovered in the feces. 6% of the ^{3}H and only trace amounts of the ^{14}C markers were recovered in the urine. These results therefore show that more than 90% of both isotopes were absorbed in the intestine.

5.3 Preclinical safety data
For soybeans phospholipids no studies on the toxicity after repeated administration are available. In toxicological studies, phosphatidylcholine (a constituent of phospholipids from soybeans) was orally administered to dogs (6 weeks) and rats (48 weeks). The NOAEL was 1000 mg/kg body weight (KG) in the dog study and 3750 mg/kg body weight in the rat study, which both corresponds approximately to 20 times the human equivalence dose.
With phospholipids from soybeans, doses up to 3750 mg/kg body weight did not affect fertility in rats (corresponds to 17 times the human equivalence dose).
Up to a dose of 1000 mg/ kg (rats) and 500 mg/ kg (rabbits) no teratogenic findings could be obtained in further studies. This corresponds to 4.5 times the human equivalence dose. However, since the studies carried out do not meet current requirements and are not complete, no final assessments of the findings on embryotoxicity can be made.
Phosphotidylcholine (a component of phospholipids from soybeans) showed no teratogenic or embryotoxic effects in therapeutic doses in animal experiments.The lowest teratogen-embryotoxic daily dose after oral administration is more than 1000 mg /kg body weight in rats and more than 500 mg /kg body weight in rabbits (equivalent to a 5.6 times human equivalence dose)..
No mutagenic potential could be found in various older studies (in vitro). There are no studies on carcinogenicity.

6. Pharmaceutical particulars
6.1 List of excipients
Hard fat, refined soy oil, hydrogenated castor oil, ethyl vanillin, 1-(4- methoxyphenyl)ethanone, 96% ethanol, gelatin, titanium dioxide (E171), iron oxide yellow (E172), iron oxide black (E172), iron oxide red (E172).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Do not use after the expiry date.

6.4 Special precautions for storage
Do not store above 30°C.

6.5 Nature and contents of container
30, 48, 60, 90 hard capsules in blisters. Not all pack sizes are marketed.

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

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