

ABBREVIATED PRESCRIBING INFORMATION (API)

Trade Name: Essentiale® Forte N Capsules

Active Ingredient: “Essential” phospholipids (EPLs) from soya bean 300 mg

Indication: Nutritional support in the management of damaged liver disease (due to chronic liver cirrhosis, fatty liver & intoxicification of hepatotoxic substances)

Dosage and Instructions for use: Initially 2 capsules 3 times daily with meals, max 6 capsules. Maintenance dose, 1 capsules 3 times daily.

Special Warning & precautions: Children under 12 years old.

May provoke severe allergic reactions. 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.

Pregnancy and lactation: The use of Essentiale Forte N is not recommended during pregnancy and lactation.

Interaction with other medicinal products: An interaction with anticoagulants cannot be excluded, dose adjustments of the anticoagulant might be necessary.

Undesirable effects: Gastrointestinal disorders such as stomach complaints, soft stool and diarrhea. Allergic reactions rarely, such as exanthema and urticaria.

Full prescription information available on request from: sanofi-aventis (Malaysia) Sdn Bhd (334110-P), 8th Floor, PNB Damansara, No 19, Lorong Dungun, Damansara Heights, 50490 Kuala Lumpur. Tel: 03-2089 3333, Fax: 03-2089 3338/9.

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