



Phospholipids + Multivitamins

Phosmax®
Capsule
LIVER THERAPY

FORMULATION:

Each capsule contains:

Phospholipids	300 mg
α-Tocopheryl Acetate (Vitamin E).....	6 mg
Thiamine Mononitrate (Vitamin B ₁).....	6 mg
Riboflavin (Vitamin B ₂)	6 mg
Nicotinamide (Vitamin B ₃)	30 mg
Pyridoxine HCl (Vitamin B ₆).....	6 mg
Cyanocobalamin (Vitamin B ₁₂).....	6 mcg

PRODUCT DESCRIPTION:

Brown cap with red body, size "0" hard gelatin capsules.

PHARMACODYNAMICS:

Phospholipids are major membrane constituents. The principal constituent of Phospholipids + Multivitamins is highly purified "essential" phospholipids, the EPL substance [active principle: Diglyceride esters of choline-phosphonic acid of natural origin, with excess of unsaturated fatty acid and oleic acid (about 70%), linolenic and oleic acid] which corresponds to the endogenous Phospholipids. EPL is rich in polyunsaturated fatty acids. The "essential" Phospholipids have been shown to be incorporated directly into the membranes of the damaged liver cells so that the liver can resume its normal function. Phospholipids + Multivitamins regulates membrane permeability and improves the exchange of substances between the intra- and extracellular space. It activates metabolic function and supports the energy balance of the liver. It restores enzyme functions and promotes detoxification of the liver. Neutral fats and cholesterol are transformed and led to their physiological oxidation. Liver cell generation is stimulated and the bile is stabilized. The major active principle is Phospholipids. In fact, this refers to Cholinophosphatide, the decisive factor of which quantitatively and therapeutically is diinoleoylphosphatidylcholine. Phospholipids form an essential element in the structure of cell membrane and cell organelles.

The functional significance of Phospholipids is based on their biphasic characteristic, which permits regulation of cell membrane penetration. They support cell-membrane functions: ion exchange, internal respiration and biological oxidation. They affect the fixation of respiratory enzymes in mitochondria and oxidative phosphorylation in the cell energy metabolism. It is known that structures on intercellular membranes and enzyme systems undergo pathological changes in synthesis meets the normal demand; in healthy people, hepatocytes contain adequate amount of Phospholipids. In liver disorders, the hepatic tissues suffers structural and functional damage. The biosynthesis of Phospholipids is hampered and its deficiency leads to impairment of cell membrane functions. The mitochondria (containing about 30% Phospholipids) are the most affected. Important metabolic process in particular, oxidative phosphorylation takes place in fat metabolism which in turn lead to fatty infiltration of the liver.

Owing its pharmacological properties, essential Phospholipids normalizes the mentioned impairments. The Phospholipids treats damaged liver, regenerates injured mitochondria, reactivates damaged enzyme system and in this way normalizes liver functions and strengthens its detoxicating role.

PHARMACOKINETICS:

Animal experiments into the pharmacokinetics showed that >90% of the orally applied radiolabeled soya bean Phospholipids are less 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 with a.o. radioactively labeled diinoleoylphosphatidylcholine (3H and 14C).

The choline moiety was 3H-labeled and the linoleic acid had the 14C-label. The maximum 3H concentration was achieved after 6-24 hrs and amounted to 19.9% of the dose.

The half-life for the choline component was 66 hrs.

The maximum 14C concentration was achieved after 4-12 hrs and amounted to 27.9% of the dose. The half-life for this component was 32 hrs.

In the faeces, 2% of the 3H and 4.5% of the 14C-label, and in the urine, 6% of the 3H and only minor amounts of the 14C-label were found.

These results show that both isotopes are absorbed to >90% in the intestine.

INDICATIONS:

Acute and Chronic Hepatitis Dystrophy and cirrhosis of the liver, biliary stasis and hepatic coma.

Liver Damaged by Toxins: Fatty liver (e.g., in diabetes, tuberculosis and chronic rheumatism), prophylaxis of recurrent gallstones, radiation damage, nephrotic syndrome and gestosis.

DOSAGE AND ADMINISTRATION:

Intensive Therapy: 1-2 capsules 3 times a day for the first 2 months.

Maintenance Therapy: 1-2 capsules 2 times a day.

To be swallowed whole, with a little liquid if desired.

Or as prescribed by the physician.

ADVERSE DRUG REACTIONS:

Phospholipids + Multivitamins is generally well tolerated. However, slight unpleasant discomforts may occur after oral intake of drug by patients prone to stomach upsets.

CONTRAINDICATION:

Hypersensitivity to the active substances or to any excipient in the formulation.

WARNINGS AND PRECAUTIONS:

Special Precautions: Due to the content in soya bean oil, Essential Phospholipids may provoke severe allergic reactions. Essential Phospholipids 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 manifests during therapy.

The physician should be consulted when complaints aggravate or when other unclear complaints occur.

PREGNANCY AND LACTATION:

Preparations from soya beans are largely used in human food, and so far, no events have been reported that would suggest any risk during pregnancy.

Specific results from investigation are not available, therefore, the use of Essential Phospholipids is not recommended during pregnancy and lactation.

OVERDOSE AND TREATMENT:

Neither overdose reaction nor symptom of intoxication has been reported to date with Essential Phospholipids.

DRUG INTERACTIONS:

An interaction of Essential Phospholipids with anticoagulants cannot be excluded; therefore, dose adjustment of the anticoagulant might be necessary.

The doctor should be consulted in case of simultaneous application.

Incompatibilities: Not applicable.

CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

"For suspected adverse drug reaction, report to the FDA: www.fda.gov/ph. Seek medical attention immediately at the first sign of any adverse drug reaction."

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.

KEEP ALL MEDICINES OUT OF CHILDREN'S REACH.

AVAILABILITY:

Alu/ PVC Blister Pack x 10's (Box of 30's)

DRP-5608-08

Date of First Authorization: December 22, 2015

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