Silibinin + Phosphatidylcholine + Multivitamins + Zinc

LIVERPRIME HD® CAPSULE

LIVER THERAPY / MULTIVITAMINS / MINERAL

FORMULATION

Silibinin-Phosphatidylcholine + Multivitamins + Zinc	
Ingredients	**Amount per Capsule**
Silibinin-Phospholipids (contains Silibinin, 29.7 to 36.3% and Phosphatidylcholine ..... 63.7 to 70.3%)	240 mg
Thiamine Mononitrate (Vitamin B_1)	6 mg
Riboflavin (Vitamin B_2)	6 mg
Pyridoxine Hydrochloride (Vitamin B_6)	6 mg
Cyanocobalamin (Vitamin B_{12})	6 mcg
Nicotinic Acid (Vitamin B_3)	10 mg
d-alpha-tocopheryl acetate (Vitamin E)	12 mg
Calcium Pantothenate	10.8 mg
Zinc (as Zinc Sulfate Monohydrate)	10 mg

PRODUCT DESCRIPTION
This product is a green opaque hard gelatin capsule.

WHAT IS IN THE PRODUCT?
Liverprime® HD contains silibinin, the main active component of silymarin (milk thistle) which is complexed to phospholipids (phosphatidylcholine) to provide synergistic support for liver health. Silibinin serves as an antioxidant, conserving glutathione in liver cells while stabilizing the liver cell membranes against oxidative attack. Silibinin also stimulates protein synthesis, supporting regeneration of liver cells. Phosphatidylcholine helps in the repair and replacement of cell membranes; it also increases the absorption of silibinin. This silibinin-phospholipid complex provides significant liver protection and enhanced bioavailability over conventional silymarin.

The product also contains vitamin E and zinc, antioxidant nutrients that help protect the liver from damaging toxins and free radicals; and B-vitamins that assist the liver in the breakdown of proteins, fats and carbohydrates into energy that the body can use.

STRENGTH OF THE PRODUCT
Please see **FORMULATION.**

WHAT IS THE PRODUCT USED FOR?
This product is used:
- To help maintain liver health
- As an adjunct in the management **(under proper medical supervision)** of a variety of liver disorders, including:
  - Acute and chronic viral hepatitis
  - Liver cirrhosis
  - Alcohol-related liver disease
  - Liver damage from certain drugs (i.e., phenothiazine and butyrophenone)
  - Fatty liver [e.g., Nonalcoholic fatty liver disease (NAFLD) or Nonalcoholic steatohepatitis (NASH)]

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS PRODUCT?
Direction for Use in Adults:
Orally, 1 capsule once to three times a day.
Or, as directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS PRODUCT?
If you are allergic to any ingredient in the product

UNDESIRABLE EFFECTS
Silibinin-phosphatidylcholine
Silibinin-phosphatidylcholine is generally well tolerated in clinical studies, even by patients with compensated cirrhosis. Reported side effects are rare and include occasional gastrointestinal (GI) distress, dyspepsia/heartburn, nausea, itching, and transient headache.

Asymptomatic liver toxicity has been observed in clinical trials involving cancer patients, in whom hyperbilirubinemia (elevated levels of bilirubin in the blood) and increases in alanine aminotransferase (ALT, a liver enzyme) levels were observed; however, these effects were present only when very high dosages of silibinin-phosphatidylcholine (between 10 and 20 g/day) were used. At high dose, a laxative effect is possible because of increased bile secretion and bile flow.

Other adverse effects reported with silibinin (or milk thistle) include abdominal pain or discomfort, flatulence/gassiness, diarrhea, loss of appetite, dizziness, urticaria (hives), eczema, and allergic/hypersensitivity and anaphylactic reactions. Excessive fullness (GI discomfort) and increased salivation have occasionally been reported with the use of phosphatidylcholine.

Nicotinic Acid
Chronic administration at doses of 3 g daily for periods greater than three months may cause nausea, heartburn, headache, fatigue, sore throat, dry hair, dry skin, tightness of the face, hives, and blurred vision.

Large doses of nicotinic acid (3 to 9 g daily) may result in elevated liver function tests and liver damage, including jaundice, cholestatic hepatitis, and portal fibrosis.

Other undesirable effects reported with high dose nicotinic acid include dizziness, diarrhea, vomiting, moderate increase in gastric secretion and bile flow; abnormal prothrombin time, and hypoalbuminemia (low albumin levels in the blood).

Zinc
Doses of zinc up to 30 mg/day are generally well tolerated. Higher doses may cause adverse reactions including nausea, vomiting, diarrhea, GI discomfort, metallic taste, headache, and drowsiness. Daily ingestion of zinc can lower high-density lipoprotein (HDL) levels. Long-term (average 6.3 years) ingestion of supplemental zinc has been linked to a significant increase in hospitalizations for urinary tract infections and kidney stones.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS PRODUCT?

Silibinin
- **Drugs metabolized by the cytochrome P450 system:** Silibinin may increase the effect of drugs metabolized by the cytochrome P450 system (e.g., clopidogrel, erythromycin, fexofenadine, nifedipine, tamoxifen, and warfarin).
- **Hypoglycemic agents:** Silibinin may decrease insulin requirements of diabetic patients with alcoholic liver cirrhosis. However, no studies suggest altered glucose metabolism in patients without liver disease. Dosage adjustment of hypoglycemic agents and monitoring of blood glucose levels may be required.
- **Metronidazole:** When used concomitantly, silibinin may reduce the effect of metronidazole.
- **Oral Contraceptives:** Silibinin may reduce the effectiveness of oral contraceptives.
- **Statins:** Silibinin may have cholesterol-lowering effects in humans.

Nicotinic Acid
- **Carbamazepine:** Nicotinic acid may decrease carbamazepine clearance.

Zinc
- **Bisphosphonates** (alendronate, etidronate, risedronate): Concomitant intake of a bisphosphonate and zinc may decrease the absorption of both the bisphosphonate and zinc.
- **Cholesterol medicines:** Additive effects are possible with concomitant administration; use with caution.
- **Copper or iron:** Concomitant administration with zinc inhibits the absorption of copper and iron. Administer zinc and copper or iron as far apart as possible.
- **Penicillamine:** Concomitant administration reduces zinc absorption.
- **Quinolones:** Zinc decreases absorption of quinolone antibiotics (e.g., ciprofloxacin, levofloxacin, ofloxacin). Zinc salts or vitamins containing zinc should be given 2 hours after or 6 hours before antibiotics.
- **Tetracycline:** Concomitant administration results in decreased tetracycline effectiveness. Administer tetracycline at least 2 hours before or 3 hours after zinc.
- **Food:** Concomitant intake of caffeine or tea and zinc reduces zinc absorption. Food containing high amounts of phosphorus, calcium (dairy), or phytates (e.g., bran, brown bread) may also reduce its absorption.

Tell your doctor about all the medicines you are taking, including other supplements and herbal products.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, just take the next dose and the subsequent doses at the usual recommended schedule.

Do not double the dose, unless recommended by a doctor.

HOW SHOULD YOU KEEP THIS PRODUCT?

- Keep the product out of sight and reach of children.
- Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Silibinin
Silibinin has generally been well tolerated in recommended doses for up to 6 years. At high doses, a laxative effect may occur.

Phosphatidylcholine
There is no reported acute or chronic toxicity from phosphatidylcholine. Daily intakes of up to 18 grams have been generally well tolerated.

Nicotinic Acid
In normal doses, nicotinic acid is not toxic, but chronic administration at doses of 3 g daily for periods greater than three months may cause adverse effects (see **UNDESIRABLE EFFECTS**).

Zinc
Signs of acute zinc toxicity (doses > 200 mg daily) include GI pain/cramps, nausea, vomiting, diarrhea, loss of appetite, headache, lethargy, muscle pain, and fever.

Chronic zinc toxicity may cause impairment of copper and iron status, anemia, and immune deficiency. Some findings have linked chronic zinc toxicity to the development of atherosclerosis because of a lowering of blood HDL levels.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE

If you have taken more than the recommended dosage, consult a doctor.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS PRODUCT

- This product should be avoided by individuals with allergies to members of the aster (*Compositae/Asteraceae*) family, daisies, artichoke, kiwi or thistle.
- Use with caution in patients taking medicines metabolized by the cytochrome P450 system (see **WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS PRODUCT**).
- This product may lower blood sugar levels. Use with caution in individuals with diabetes or hypoglycemia, or those taking medicines or supplements that affect blood sugar levels.
- Those with malabsorption problems may develop diarrhea or steatorrhea (presence of excess fat in feces) when using phosphatidylcholine supplements.
- Those with antiphospholipid-antibody syndrome should exercise caution in the use of phosphatidylcholine supplements.
- Large doses of nicotinic acid (> 300 mg/daily) should be used with caution in patients with gallbladder disease or a history of jaundice or liver disease, diabetes mellitus, gout, peptic ulcer, or allergy.
- Do not take more than the recommended dose.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

- If any undesirable effect occurs.
- Consult your doctor before using this product:
  - If you are pregnant and/or breastfeeding
  - If you have liver disease or active peptic ulcer

ADVERSE DRUG REACTION REPORTING STATEMENT
For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph **AND** Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY

Silibinin-Phosphatidylcholine + Multivitamins + Zinc (LIVERPRIME® HD) 240 mg Capsule in aluminum flex foil, Box of 100s.

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