Livosil®-B CAPSULES

1. Generic Names

Silymarin

Thiamine Mononitrate [Vitamin B1] I.P.

Riboflavin [Vitamin B2] I.P.

Pyridoxine Hydrochloride [Vitamin B6] I.P.

Niacinamide I.P.

Calcium Panthothenate I.P.

Vitamin B12 I.P.

2. Qualitative and Quantitative Composition

Silymarin	70 mg
Thiamine Mononitrate [Vitamin B1] I.P.	5 mg
Riboflavin [Vitamin B2] I.P.	5 mg
Pyridoxine Hydrochloride [Vitamin B6] I.P.	1.5 mg
Niacinamide I.P.	25 mg
Calcium Panthothenate I.P.	7.5 mg
Vitamin B12 I.P.	5 mcg

3. Dosage form and strength

Capsules for oral administration.

4. Clinical particulars

4.1 Therapeutic indication

Livosil –B is indicated in patients with

- Acute and chronic viral hepatitis
- Alcoholic Liver Disease
- Early stages of Cirrhosis
- Drug induced toxicity
- Fatty liver

4.2 Posology and method of administration

As directed by physician.

4.3 Contraindication

Livosil-B is contraindicated in patients with Hypersensitivity to components of the formulation.

4.4 Special warnings and precautions for use

In theory, Silymarin may lower blood sugar levels. Caution is advised in patients with diabetes or hypoglycemia, and in those taking drugs that affect blood sugar. Serum glucose levels may need to be monitored.

4.5 Drug interactions

No drug interactions could be found with Livosil-B Capsule. The influence that Silymarin has on liver function should be taken into account when pharmaceutical drugs are given concomitantly.

4.6 Use in special population

- Pediatric: Safety and effectiveness of Livosil-B in pediatric patients have not been established.
- Geriatric: Safety and effectiveness of Livosil-B in geriatric patients have not been established.
- Liver impairment: Safe.
- Renal failure: No data available.
- Pregnancy and lactation: There are currently no adequate and well-controlled trials with Silymarin in pregnant and lactating women. Livosil-B Capsule should be used only when clearly needed.

4.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Livosil-B capsule is known.

4.8 Undesirable effects

Silymarin is reported to have a very good safety profile. Both animal and human studies showed that silymarin is non-toxic even when given at high doses (>1500 mg/day). However, a laxative effect is noted at these doses, which may be due to increased bile secretion and bile flow. Other commonly noted adverse effects are: bloating, dyspepsia, nausea and irregular stools. Silymarin may also cause an allergic reaction in some individuals, particularly those with known allergies to plants in the Asteraceae family (thistles, daisies, artichokes). No other widely reported side effects are known when Silymarin is taken in proper therapeutic dosages.

4.9 Overdose

There is limited experience of overdose with Livosil-B capsules. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 Mechanism of action

Livosil-B Capsule is a unique combination of Silymarin with vitamins of the B Complex group. The hepatoprotective effects of Livosil-B Capsule are accomplished via several mechanisms including:

- Anti-oxidation
- inhibition of lipid peroxidation
- enhanced liver detoxification and glucuronidation
- protection of glutathione depletion

Studies have also shown that Livosil-B Capsule exhibits:

- anti-inflammatory effects, including inhibition of leukotriene and prostaglandin synthesis, mast cell stabilization, and inhibition of neutrophil migration
- increase hepatocyte protein synthesis, thereby promoting hepatic tissue regeneration
- Reduces the conversion of hepatic stellate cells into myofibroblasts, slowing or even reversing fibrosis.

Clinical studies have demonstrated Livosil-B Capsule to have immunomodulatory effects on the diseased liver.

The combination of Silymarin with Vitamin B complex in Livosil-B Capsule provides for a comprehensive therapy of various liver disorders. Silymarin is not water soluble; therefore it is usually administered orally in encapsulated form. Silymarin is readily absorbed from the gastrointestinal tract. In animals and humans, peak plasma levels are reached in four to six hours after an oral dose. Silymarin is excreted primarily via the bile but some clearance is also achieved via the kidneys. The clearance half-life of Silymarin is six to eight hours.

5.2 Pharmacodynamic properties

No data available.

5.3 Pharmacokinetic properties

No data available.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Silymarin is an active principle obtained from milk thistle seed (Silybum marianum) . It is a mixture of flavonolignans, consisting of silibinins A and B, isosilibinins A and B, silicristin, and silidianin It might protect liver cells from toxic chemicals and drugs. It also seems to have antioxidant and anti-inflammatory effects. Milk thistle plant extract might enhance the effects of estrogen.

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months.

8.3 Packaging Information

Livosil-B is available in blister of 10 capsules

8.4 Storage and handling instructions

Store in cool and dry place.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by CENTAUR PHARMACEUTICALS PVT. LTD..

11. Details of permission or license number with date

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