1. Name of the Medicinal Product

Silymarin tablets

SILYBON 140

2. Qualitative and Quantitative Composition

Each film coated tablet contains Silymarin (as Silybin) 140 mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical Form

Film coated tablet

Orange coloured, circular, biconvex, film-coated tablets with 'MICRO' engraved on both the sides

4. Clinical Particulars

4.1 Therapeutic indications

Silymarin is useful in the treatment of:

- Infective hepatitis
- Alcoholic liver disease
- Toxic metabolic liver damages (e.g. fatty infiltration of liver), mushroom poisoning, carbon tetrachloride poisoning.

4.2 Posology and method of administration

The usual recommended dose of Silymarin is 140 mg, three times a day, in mild to moderate cases. In severe cases 140 mg three times a day. Depending on the grade and severity of the liver disease 4 weeks treatment is essential for infective hepatitis and for severe and chronic cases, the treatments may be continued as long as clinically indicated.

4.3 Contraindications

The product is contraindicated in patients hypersensitive to Silymarin or any other ingredient. In rare instances, a laxative effect may occur due to increased liver function.

4.4 Special warning and precautions

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 Interaction with other medicinal products and other forms of interactions

No drug interaction has been reported with other drugs.

4.6 Fertility, pregnancy and lactation

There are currently no adequate and well-controlled trials with Silymarin in pregnant and lactating women. Silymarin should be used only after detailed analysis of risk and benefit ratio.

4.7 Effects on ability to drive and use machines

Silymarin has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Silymarin is reported to have a very good safety profile. Both animal and human studies show that Silymarin is non-toxic even when given at high doses (>1500 mg/day). However, a laxative effect is noted at the prescribed dose, 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 of Asteraceae family (thistles, daisies, artichokes). No other widely reported side effects are known when Silymarin is taken in proper therapeutic dosages.

4.9 Overdose:

No particular antidote is available for the treatment of overdose. The signs and symptoms should be treated symptomatically.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Silymarin, the active principle of the fruit of Silybon marianum, acts as a cell membrane stabilizer and protects the liver against deleterious agents. Silymarin directs action to liver cells, protects its membrane integrity, stabilizes and strengthens membranes of cell organs and nuclei in the cell to prevent mutation and death of the cells by toxic substances thus increasing liver function. Silymarin can also enhance the metabolic function of liver cell, repair damaged liver cell, accelerate rebirth of liver cell, and prevent fatty acid change of liver cell caused by alcohol, reduced glycogen content and mitochondrial alteration.

5.2 Pharmacokinetic Properties

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 undergoes significant hepatic metabolism. 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.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

6. Pharmaceutical Particulars

6.1 List of excipients

Microcrystalline cellulose
Dicalcium phosphate anhydrous
Colloidal silicon dioxide
Methyl Paraben
Propyl Paraben
Maize starch
Microcrystalline cellulose
Sodium starch glycolate
Talc
Magnesium stearate
Hydroxy propyl methyl cellulose
Titanium dioxide
Talc
Polysorbate-80
Sunset yellow lake

6.2 Incompatibilities

None known

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

Keep the containers tightly closed. Keep in a cool dry place.

6.5 Nature and contents of container

Blister pack of 10 Tablets

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder

Manufacturer Name and Address:
Micro Labs Limited,
92, SIPCOT HOSUR-635-126,INDIA

Applicant Name and Address:
MICRO NOVA PHARMACEUTICALS IND LTD,
Plot 3, Billings Way, Oregun

Address of the manufacturing site:

MICRO LABS LIMITED

92, SIPCOT Industrial Complex

Hosur, Tamilnadu-635126, INDIA

8. Marketing Authorization Numbers

4571204

9. Date of first authorization

10.04.2012

10. Date of revision of the text

Jan 2023