SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

SILYBON 70/140

2. Qualitative and quantitative composition

Each film-coated tablet contains Silymarin (as Silybin) …….70/140mg

3. Pharmaceutical form

Tablets 70/140mg, for oral administration

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

4. Clinical particulars

4.1 Therapeutic indications

Toxic liver damage: for supportive treatment in patients with chronic inflammatory diseases of the liver or hepatic cirrhosis.

Note: This medicine is not suitable for treating cases of acute poisoning

4.2 Posology and method of administration

The usual recommended dose of Silymarin is 70 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

Silymarin should not be administered in cases of known hypersensitivity against milk thistle fruits, other composites or any of the excipients

4.4 Special warnings and precautions for use

The treatment with this medicinal product does not serve as a substitute for the abstention from the cause of liver damage (e.g. alcohol). If icterus (light to dark yellow tinge of the skin, yellow discoloration of the white of the eye) occurs the doctor is to be consulted.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

There is no information on the experience of using this drug in pregnant women. Animal studies are not enough with respect to the study of reproductive toxicity. Therefore, the use of the drug during pregnancy is not recommended. It is not known whether the active components of the drug and their metabolites are excreted in human breast milk. The risk to newborns / infants cannot be excluded. Therefore, the use of the drug during breastfeeding is not recommended. Research data on the effect of active components on fertility are insufficient

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

Like all medicinal products, Silymarin can have undesirable effects. For the evaluation of undesirable effects, the following terms of frequency are used: Very common: common: uncommon: rare: Very rare: more than 1 of 10 patients less than 1 of 100 patients, but more than 1 of 100 patients less than 1 of 100 patients, but more than 1 of 1,000 patients less than 1 of 1,000 patients, but more than 1 of 10,000 patients less than 1 of 10,000 patients, including isolated reports. In rare cases gastrointestinal disorders, as e.g. a mild laxative effect, have been observed. Very rarely hypersensitivity reactions, like rash or dyspnoea, can occur.

Reporting of suspected adverse reactions": Healthcare professionals are requested to report any suspected adverse reactions via the national regulatory authority.

4.9 Overdose

Signs or symptoms of over dosage or poisoning have not hitherto been observed. The undesirable effects described above can be amplified. A special antidote is not known. If necessary, symptomatic measures are recommended.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: medicinal products for liver therapy, ATC code: A05BA03 The antitoxic efficacy of Silymarin has been demonstrated in animal experiments in numerous models of liver damage, e.g. with poisons of the death cap fungus phalloidin and alpha-amantin, with lanthinides, carbon tetrachloride, galactosamine, thiocetamine and the hepatotoxic frog virus FV3. The therapeutic effect of silymarin is attributable to the fact that it has several sites of mechanisms of action: Because of its radical capturing powers, Silymarin possesses antiperoxidative activity. The

pathophysiological process of lipid peroxidation which is responsible for the destruction of cell membranes, is interrupted or prevented. Furthermore, in liver cells, which have already sustained damage, Silymarin stimulates protein synthesis and normalises phospholipid metabolism. The overall outcome is that the cell membrane is stabilized and loss of dissolved cell constituents (e.g. transaminases) from the liver cell is restricted or prevented.

Silymarin restricts certain hepatotoxic substances (poisons of the death cap fungus) from gaining entry to the cell. The enhancement of protein synthesis by Silymarin is due to its stimulation of RNA polymerase I, an enzyme which is located in the nucleus. This leads to increased formation of ribosomal RNA and structure and function proteins (enzymes) are therefore synthetized in greater amounts. The outcome is an increase in the repair capacity and the regenerative powers of the liver.

5.2 Pharmacokinetic properties

The principal constituent of silymarin is silibinin. Clinical investigations show that after its absorption in the digestive tract, it is excreted mainly in the bile (> 80 per cent of the amount absorbed). As metabolites, glucoronides and sulphates have been demonstrated in the bile, silibinin is assumed to be reabsorbed after being deconjugated, and then enters into an enterohepatic circulation, as has been shown in experimental animals. As might be expected from its predominantly biliary elimination (site of action: liver), blood levels are low and renal elimination is small. The absorption half-life is 2.2 h and the elimination half-life 6.3 h. When silymarin is given in therapeutic doses (140 mg silymarin 3 times daily), the levels of silibinin found in human bile are the same after repeated doses and after a single dose. The results show that silibinin does not accumulate in the body. After repeated administration of silymarin in doses of 140 mg 3 times daily biliary elimination reaches a steady state

5.3 Preclinical safety data

n/a

6. Pharmaceutical particulars

6.1 List of excipients

Microcrystalline Cellulose BP

Dibasic Calcium Phosphate BP (Anhydrous)

Colloidal Anhydrous Silica BP (Aerosil-200)

Methyl Hydroxy Benzoate BP (Methyl Paraben)

6.2 Incompatibilities

n/a

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C. Keep out of the reach of children

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 authorisation holder

MICRO LABS LIMITED

No.31, Race Course Road

Bangalore-560 001

India

8. Marketing authorisation number(s)

H2009/20556/404

9. Date of first authorisation/renewal of the authorisation

14/08/2026

10. Date of revision of the text