

Appendix 3

Sunmarin Capsules

Product Description:

This product is a yellow–brown powder, has a characteristic taste and odor, filled in the No.0 capsules. The color of capsular cap and body are dark red, and the capsular cap is printed with white CH-101.

Name and Strength of Active Substance:

Each capsule (filled weight: 450 mg) contains Exsiccated Fructus Cardui Mariae Extract 300 mg (Equivalent to 150 mg of Silymarin calculated as Silybin)

Sources (animal origin): This product contains substance from animal origin.

Source of gelatin in capsule shell : Bovine

Indication:

Traditionally used as liver tonic.

Dose/Use Instruction:

Adult: Take 2 capsules each time with food.

Frequency of administration: Once daily.

Contraindication:

Not known.

Warnings and Precautions:

This is a traditional medicine. Please consult your pharmacist/doctor before taking this product. Keep out of reach of children & *Jauhkan daripada capaian kanak-kanak*.

Statement on Usage during Pregnancy and Lactation:

Insufficient reliable data.

Adverse Effects/Undesirable Effects:

Mild gastrointestinal symptoms such as dry mouth, nausea, upset stomach, gastric irritation and diarrhoea may occur; headache; allergic reactions (dermatitis, urticaria, skin rash, pruritus, anaphylaxis, asthma), have been reported. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

Interactions with Other Medications:

The concomitant use of Silymarin and butyrophenones or phenothiazines result in a reduction of lipid peroxidation. Silymarin has an antagonistic effect with yohimbine and phentolamine when given simultaneously.

Overdose and Treatment:

Unknown

Storage Conditions:

Store away from direct light, heat and moisture; Store in a cool place below 30°C.

Dosage Forms and Packaging Available:

Capsules

10 capsules/PTP×9/box

Name and Address of Manufacturer:

Taiwan Biotech Co., Ltd.

22, Chieh Shou Rd.,

Taoyuan Dist., Taoyuan City,

Taiwan, R.O.C.

Name and Address of Product Registration Holder:

Imported by Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd.

9,11 & 17, Jalan Kempas 4,

Taman Perindustrian Tampoi Indah,

81200 Johor Bahru,

Johor Malaysia.

Other Importer

Sunward Pharmaceutical Pte. Ltd.

11, Wan Lee Road,

Jurong,

Singapore 627943.

Date of Revision of Package Insert:

March 2019