

PROPRIETARY NAME AND DOSAGE FORM

MILK THISTLE (capsule)

COMPOSITION

Each capsule contains: Active ingredient: Milk Thistle (*Silybum marianum*) leaves powder 300 mg and Milk Thistle (*Silybum marianum*) extract (80% Silymarin) 30 mg.

*Capsules are free of gluten, preservatives, sugar and lactose.

PHARMACOLOGICAL CLASSIFICATION

D 33.6 Western herbal medicine.

Discipline: Western herbal.

INDICATIONS

This product is used to support normal liver function and assist with symptoms associated with occasional over indulgence of food and drinks. This is based on traditional use only.

CONTRA-INDICATIONS

Do not use this medicine if you are hypersensitive (allergic) to any of the ingredients in the formulation. Not suitable for children younger than 12 years, unless under medical supervision. Avoid use if you have gallstones, stomach ulcers or hormone sensitive cancer (such as breast cancer).

WARNINGS AND SPECIAL PRECAUTIONS

If you suffer from any serious ailments or conditions (such as cirrhosis of the liver); or if you are taking any prescribed medication (including blood thinning medication), please check with your healthcare provider before taking this medicine.

- This medicine might decrease blood sugar levels and people with diabetes must monitor sugar levels more often.
- People that are allergic to the Asteraceae/Compositae family (such as marigolds, daisies, ragwood etc.), could react adversely to this medicine. Please consult your healthcare provider before using this medicine.
- No studies on the effect on the ability to drive and use machines have been performed. Please exercise care when driving or operating machinery until you know how it affects you.
- Porphyria: Safety has not been established.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

PREGNANCY AND LACTATION

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

INTERACTIONS

If you are taking other medicines regularly, including complementary or traditional medicines, or start taking any additional medicines while taking this medicine, consult your healthcare provider for advice. Milk thistle may interfere with the way the body processes certain drugs using the liver's 'cytochrome P450' enzyme system. As a result, the levels of these drugs may be altered in the blood, and may cause decreased efficacy or potentially serious adverse reactions. Anyone using other medications is advised to consult with their healthcare provider about possible interactions before taking this medicine.

DOSAGE AND DIRECTIONS FOR USE

Take one capsule twice a day with meals, or as directed by your healthcare provider.

SIDE EFFECTS

Side effects can include an upset stomach, nausea and bloating. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, discontinue use immediately and consult your doctor, pharmacist or other healthcare provider for advice.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

No known symptoms of overdose. Treatment is symptomatic and supportive.

IDENTIFICATION

White capsule.

PRESENTATION

30 Capsules are packed in a plastic container.

STORAGE INSTRUCTIONS

Store all medicines out of reach of children. Store in a cool dry place below 25 °C and keep away from direct sunlight. Keep the container tightly closed.

NAPPI CODE

722638001

NAME AND BUSINESS ADDRESS OF THE APPLICANT

Alveta Healthcare (Pty) Ltd, 1 Greenwich Grove, Station Road, Rondebosch, 7700. Company registration number: 2004/021899/07. Pharmacy audit number: Y53008.

DATE OF PUBLICATION OF THE PACKAGE INSERT

September 2017.

HANDELSMERKNAAM EN DOSEERVORM

MILK THISTLE (kapsule)

SAMESTELLING

Elke kapsule bevat: Aktiewe bestanddeel: Melkdissel (*Silybum marianum*) blaarpoeier 300 mg en Melkdissel (*Silybum marianum*) uittreksel (80% Silymarin) 30 mg.

*Kapsules bevat geen gluteen, preserveermiddels, suiker of laktose nie.

FARMAKOLOGIESE KLASSIFIKASIE

D 33.6 Westerse kruie medisyne.

Dissipline: Westerse kruie.

INDIKASIES

Hierdie produk word gebruik om normale lewerfunksie te ondersteun en help met simptome wat geassosieer word met die oormatige inname van kos en drank. Hierdie is slegs gebaseer op tradisionele gebruik.

KONTRA-INDIKASIES

Vermý as jy hipersensitief (allergies) is vir enige van die bestanddele in die formule. Dit is nie geskik vir kinders jonger as 12 jaar nie, behalwe onder die toesig van 'n geneesheer. Vermý gebruik indien jy galstene, 'n maagseer of hormoonsensitiewe kanker (soos borskanker) het.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

As jy enige voorgeskrewe medisyne (insluitend bloedverduunningsmedikasie) gebruik, of aan enige ernstige siektes of toestande (soos lewer siektes) ly, raadpleeg jou geneesheer voordat jy hierdie medisyne begin gebruik.

- Hierdie medisyne kan moontlik bloedsuikervlakke beïnvloed en diabeete moet hulle suikervlakke meer gereeld monitor.
- Individue wat allergies is vir die Asteraceae/Compositae familie (soos bv. marigold, madeliefies, ragwood ens.) moet die medisyne onder mediese toesig gebruik aangesien dit 'n allergiese reaksie kan veroorsaak.
- Geen studies is gedoen om die effek wat die medisyne het op bestuur en die gebruik van masjinerie vas te stel nie. Wees asseblief versigtig wanneer jy bestuur of masjinerie gebruik totdat jy weet hoe die medisyne jou beïnvloed.
- Porfirie: Veiligheid is nie vasgestel nie.

Voedingsaanvullings moet nie 'n gebalanseerde dieët vervang nie. Moenie die aanbevole dosis oorskry sonder om 'n geneesheer te raadpleeg nie.

SWANGERSKAP EN BORSVOEDING

Indien jy swanger is of borsvoed, raadpleeg jou geneesheer voordat jy hierdie medisyne gebruik.

INTERAKSIES

As jy ander medisyne gereeld gebruik, insluitend aanvullende (komplimentêre) of tradisionele medisyne, of as jy enige addisionele medisyne begin neem terwyl jy hierdie medisyne gebruik, raadpleeg jou geneesheer vir raad. Melkdissel kan inmeng met die metabolisme van sekere medisyne wat gemetaboliseer word via die lewer se 'sitochroom P450' ensiemstelsel. As gevolg van hierdie interaksie kan die vlakke van sekere middels verander in die bloedstroom wat kan lei tot oneffektiwiteit of potensieel ernstige newe-effekte. Indien jy enige ander medikasie gebruik, raadpleeg jou geneesheer vir raad aangaande enige interaksies voordat jy hierdie medikasie begin gebruik.

DOSIS EN GEBRUIKSAANWYSINGS

Neem een kapsule twee maal per dag met etes, of soos jou geneesheer voorskryf.

NEWE-EFFEKTE

Newe-effekte kan omgekrapte maag, naarheid en opgeblaasheid insluit. Sommige aangemelde newe-effekte is nie in hierdie voubiljet ingesluit nie. Indien jy enige onaangename newe-effekte ervaar of voel dat jou algemene gesondheid verswak, hou onmiddellik op om die medisyne te gebruik en kontak jou geneesheer.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING

Simptome van oordosering is onbekend. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

Wit kapsule.

AANBIEDING

30 Kapsules verpak in 'n plastiek houer.

BERGINGSAAANWYSINGS

Berg alle medisyne buite bereik van kinders. Berg in 'n koel, droë plek onder 25 °C en hou weg van direkte sonlig. Hou die houer dig toe.

NAPPI KODE

722638001

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT

Alveta Healthcare (Pty) Ltd, Greenwich Grove 1, Station weg, Rondebosch, 7700. Maatskappy registrasie nommer: 2004/021899/07. Apteek oudit nommer: Y53008.

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