



Milk Thistle

Liver Tonic

PACKAGE INSERT OF MILK THISTLE LIVER TONIC

Western Herbal Complementary Medicine and Health Supplement.

MILK THISTLE LIVER TONIC is unregistered and has not been evaluated by SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS

Not scheduled

NAME OF THE MEDICINE

MILK THISTLE LIVER TONIC Capsules

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each Capsule contains

Silybum marianum (Milk Thistle) **300 mg**

Silybum marianum (Milk Thistle extract) **50 mg**

Taraxacum mangolicum (Dandelion) **150 mg**

Phyto Amino Chelate Complex **50 mg**

PHARMACEUTICAL FORM

Capsule, MILK THISTLE LIVER TONIC: mottled grayish brown capsule with a characteristic herbal taste.

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS

MILK THISTLE LIVER TONIC is a Western Herbal Complementary and Health Supplement, traditionally used for assisting in improving liver function, and assisting in the protection against liver poisons and strain caused by alcohol, dietary or drug abuse or exposure to chemical pollution. It is also known to assist in detoxifying and aiding in internal cleansing properties.

Dandelion, one of the actives in MILK THISTLE LIVER TONIC, contains chemicals that may increase urine production, prevent crystals from forming in the urine, and decrease inflammation.

POSOLOGY AND METHOD OF ADMINISTRATION

Take 1 or 2 Capsules daily with or after meals, 2 hours before or after antibiotics or as directed by your health practitioner.

CONTRAINDICATIONS

- Hypersensitivity to the active substances, allergies to Asteraceae/Compositae plants, chrysanthemums, daisies, marigolds or to any of the excipients of MILK THISTLE LIVER TONIC.
- Since milk thistle exerts a mild estrogen-like effect, it is contraindicated in patients with hormone-sensitive conditions like endometriosis, uterine fibroids, or cancers of the breast, uterus, or ovaries.
- MILK THISTLE LIVER TONIC is contraindicated in pregnancy and lactation

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

- MILK THISTLE LIVER TONIC may interact with antibiotics reducing absorption of quinolones; therefore, it is advisable to take this medication 2 hours before or after antibiotics.
- Due to risk of hyperkalaemia patients with renal failure or heart failure should avoid MILK THISTLE LIVER TONIC.
- Women with hormone sensitive conditions should avoid milk thistle.
- MILK THISTLE LIVER TONIC may lower blood sugar levels. Caution is advised in people with diabetes or low blood sugar.
- Dandelion might slow blood clotting and might increase the risk for bruising and bleeding in people with bleeding disorders.
- Dandelion might have an effect like a water pill or "diuretic". Taking MILK THISTLE LIVER TONIC might decrease how well the body gets rid of lithium. This could increase how much lithium is in the body and result in serious side effects.
- Dandelion might increase the effects of diabetes medications and might increase the risk of blood sugar becoming too low. Monitor your blood sugar closely.

INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

Milk Thistle

- Milk thistle may reduce your blood sugar, so it needs to be used with caution as it may trigger hypoglycaemia in people on diabetes medications.
- Milk thistle may also reduce the effectiveness of estrogen-based contraceptives.
- Milk thistle can change the way that your body metabolizes certain drugs in the liver, triggering interactions with:
 - Antibiotics like clarithromycin
 - Anticoagulants like warfarin
 - Nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen, celecoxib, and diclofenac
 - Statin drugs like lovastatin and fluvastatin

Dandelion

- Taking MILK THISTLE LIVER TONIC along with antibiotics might decrease the effectiveness of some antibiotic that include ciprofloxacin, enoxacin, norfloxacin, sparfloxacin, trovafloxacin and grepafloxacin
- Some medications are changed and broken down by the liver. Dandelion might decrease how quickly the liver breaks down some medications and can increase the effects and side effects of some medications like amitriptyline, haloperidol, ondansetron, propranolol, theophylline, verapamil and others
- Dandelion might increase how quickly some medications are changed by the liver and could decrease how well some of these medications work. These medications include acetaminophen, atorvastatin, diazepam, digoxin, entacapone, estrogen, irinotecan, lamotrigine, lorazepam, lovastatin, meprobamate, morphine, oxazepam and others
- Dandelion contains significant amounts of potassium. Some "water pills" can also increase potassium levels in the body. Taking some "water pills" along with dandelion might cause too much potassium to be in the body. Medication that increase potassium in the body include amiloride, spironolactone, and triamterene.
- Dandelion might interact with diabetes medication such as glimepiride, glyburide, insulin, pioglitazone, rosiglitazone and others. The dose of your diabetes medication might need to be changed.
- Taking dandelion along with medications that also slow clotting might increase the chances of bruising and bleeding. Some medications that slow blood clotting include aspirin, clopidogrel, diclofenac, ibuprofen, naproxen, dalteparin, enoxaparin, heparin, warfarin and others.

FERTILITY, PREGNANCY AND LACTATION

Women who are breastfeeding or pregnant should avoid taking MILK THISTLE LIVER TONIC. Because of the hormonal effects of some of the ingredients in MILK THISTLE LIVER TONIC it is not advised during pregnancy and lactation.





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EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effect is unknown. However, do take care if you take MILK THISTLE LIVER TONIC until you know how it will affect you.

UNDESIRABLE EFFECTS

MILK THISTLE LIVER TONIC is well tolerated although some of the following side effects could occur in certain individuals.

Milk Thistle

- Milk thistle may trigger a number of side effects, including headache, nausea, diarrhea, abdominal bloating, and gas. Less commonly, muscle aches, joint pain, and sexual dysfunction have been reported.
- People with allergies to ragweed, daisies, artichokes, kiwi, or plants in the aster family may also be allergic to milk thistle. On rare occasions, milk thistle can cause a potentially life-threatening, all-body allergy known as anaphylaxis. If left untreated, anaphylaxis can lead to shock, coma, cardiac or respiratory failure, or death.

Dandelion

- People with eczema seem to have a higher chance of having an allergic reaction to dandelion, be sure to check with your healthcare provider before taking MILK THISTLE LIVER TONIC
- Dandelion might slow blood clotting.
- Dandelion might reduce how much oxalate is released through urine.
- Taking dandelion by mouth might cause stomach discomfort, diarrhea, or heartburn in some people.

REPORTING OF SUSPECTED ADVERSE REACTIONS.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to:

- SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>
- CONTEGO PHARMACEUTICALS (Pty) Ltd 250 Nadine Street, Robertville, Roodepoort Gauteng, South Africa

OVERDOSE

Treatment should be symptomatic and supportive.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES

Pharmacological classification: D 32.16 Other – Western Herbal Complementary Medicine
Silymarin is a principle component of milk thistle and is said to have both an anti-inflammatory and antioxidant effect. The therapeutic activity of which is based on two mechanisms of action, Silymarin may prevent penetration of liver toxins into the interior of the hepatocyte and it may stimulate the regenerative ability of the liver and the formation of new hepatocytes. Milk thistle extract provides hepatocellular protection by stabilizing hepatic cell membranes.

Dandelion has been shown to act as a cholagogue, increasing the flow of bile. It has diuretic action and is also a rich source of potassium.

Amino acids are the essential and branched chain amino acids and needed for the growth and repair of organs and tissues.

PHARMACOKINETIC PROPERTIES

Milk thistle has been used traditionally for over 2000 years, most commonly for improving and supporting liver function and gallbladder disorders.

Dandelion has been used to treat disturbances in bile flow, loss of appetite, and heartburn. It also acts as a diuretic.

Amino acids are the building blocks from which the body creates proteins and assists in liver rejuvenation

PHARMACEUTICAL PARTICULARS

LIST OF EXCIPIENTS

Dicalcium Phosphate, Magnesium Stearate, Microcrystalline Cellulose PH 102, Starch 1500

INCOMPATIBILITIES

Not applicable

SHELF LIFE

2 years

SPECIAL PRECAUTIONS FOR STORAGE

Store well closed, at or below 25 °C out of direct sunlight | KEEP OUT OF REACH OF CHILDREN.

NATURE AND CONTENTS OF CONTAINER

MILK THISTLE LIVER TONIC Capsules are packed in white plastic containers with a white screw-on-cap containing 60 Capsules. Each plastic container is packed into an outer carton.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

No special requirements.

HOLDER OF CERTIFICATE OF REGISTRATION

Contego Pharmaceuticals (Pty) Ltd
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REGISTRATION NUMBER

To be allocated.

DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be allocated.

