PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

GENOLOGIX MILK THISTLE EXTRACT 500mg hard capsules

Milk thistle (Silybum marianum) seed extract 500 mg per daily dose (2 capsules, each containing 250 mg), providing 400 mg silymarin

Sugar free

COMPLEMENTARY MEDICINE

Western Herbal Medicine

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

This leaflet is also available in Afrikaans on the product pages at https://genologix.co.za/product/genologix-milk-thistle-extract-500mg-30-days-supply/ (30-day pack) and https://genologix.co.za/product/genologix-milk-thistle-extract-500mg-bulk-120-days-supply/ (120-day pack).

Read all of this leaflet carefully because it contains important information for you

Genologix Milk Thistle Extract 500mg is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Genologix Milk Thistle Extract 500mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Genologix Milk Thistle Extract 500mg with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What Genologix Milk Thistle Extract 500mg is and what it is used for
2. What you need to know before you take Genologix Milk Thistle Extract 500mg
3. How to take Genologix Milk Thistle Extract 500mg
4. Possible side effects
5. How to store Genologix Milk Thistle Extract 500mg
6. Contents of the pack and other information

1. What Genologix Milk Thistle Extract 500mg is and what it is used for

Genologix Milk Thistle Extract 500mg is a Western herbal medicine. It contains an extract of the seeds of the milk thistle plant (*Silybum marianum*), standardised to silymarin, the plant's main group of natural compounds.

Genologix Milk Thistle Extract 500mg:

- is traditionally used in Western herbal medicine to support healthy liver function; and
- is traditionally used in Western herbal medicine to relieve mild digestive discomfort, such as a feeling of fullness and flatulence (wind).

If symptoms persist or get worse, consult your doctor or other health care provider. Genologix Milk Thistle Extract 500mg is not intended to treat liver disease.

2. What you need to know before you take Genologix Milk Thistle Extract 500mg

Do not take Genologix Milk Thistle Extract 500mg:

- if you are hypersensitive (allergic) to milk thistle or other plants of the daisy family (Asteraceae/Compositae), such as ragweed, chrysanthemums, marigolds or daisies or any of the other ingredients of Genologix Milk Thistle Extract 500mg (listed in section 6).

Warnings and precautions

Take special care with Genologix Milk Thistle Extract 500mg. Talk to your doctor or pharmacist before taking it:

- if you have, or think you may have, liver disease. See a doctor if you get yellowing of the skin or eyes, dark urine, pale stools or pain in the upper abdomen;
- if you have diabetes or take medicine to lower your blood sugar;
- if you have a hormone-sensitive condition (e.g. breast, uterine or ovarian cancer, endometriosis or uterine fibroids);

- if you take any of the medicines listed under “Other medicines and Genologix Milk Thistle Extract 500mg”.

Children and adolescents

Do not give Genologix Milk Thistle Extract 500mg to children and adolescents under 18 years of age. Its safety in this age group has not been established.

Other medicines and Genologix Milk Thistle Extract 500mg

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Milk thistle may change how the body breaks down some medicines. Talk to your doctor or pharmacist before you take it if you take:

- medicines for diabetes (blood sugar may drop too low);
- warfarin or other medicines that thin the blood;
- tamoxifen, or medicines containing oestrogen (e.g. hormone replacement therapy, some contraceptives);
- statins (cholesterol medicines);
- any other medicine that is broken down by the liver.

Genologix Milk Thistle Extract 500mg with food, drink and alcohol

For best results, take Genologix Milk Thistle Extract 500mg on an empty stomach. No interactions with drinks are known.

Pregnancy, breastfeeding and fertility

The safety of Genologix Milk Thistle Extract 500mg in pregnancy and breastfeeding has not been established. Genologix Milk Thistle Extract 500mg is not recommended if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

Genologix Milk Thistle Extract 500mg is not expected to affect your ability to drive or use machines.

It is not always possible to predict to what extent Genologix Milk Thistle Extract 500mg may interfere with your daily activities. Do not drive, operate machinery or take part in activities that need you to be alert until you know how Genologix Milk Thistle Extract 500mg affects you.

Genologix Milk Thistle Extract 500mg contains

Genologix Milk Thistle Extract 500mg contains no sugar and no sweeteners.

3. How to take Genologix Milk Thistle Extract 500mg

Do not share medicines prescribed for you with any other person.

Always take Genologix Milk Thistle Extract 500mg exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults (18 years and older): take two (2) capsules once a day. This provides 400 mg of silymarin.

Do not take more than two (2) capsules in 24 hours.

Children and adolescents under 18 years: Genologix Milk Thistle Extract 500mg is not intended for this age group.

How to take it:

1. Take the capsules on an empty stomach.
2. Swallow the capsules whole with a glass of water.
3. Stop taking Genologix Milk Thistle Extract 500mg if you get any side effects (see section 4).

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

If you take more Genologix Milk Thistle Extract 500mg than you should

If you take too many capsules, you may get an upset stomach, bloating or loose stools.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Genologix Milk Thistle Extract 500mg

If you forget a dose, take your next dose at the usual time the next day.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Genologix Milk Thistle Extract 500mg

You can stop taking Genologix Milk Thistle Extract 500mg at any time. No withdrawal effects are expected.

4. Possible side effects

Genologix Milk Thistle Extract 500mg can have side effects.

Not all side effects reported for Genologix Milk Thistle Extract 500mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Genologix Milk Thistle Extract 500mg, please consult your health care provider for advice.

If any of the following happens, stop taking Genologix Milk Thistle Extract 500mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Genologix Milk Thistle Extract 500mg. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown:

- upset stomach, nausea (feeling sick) or bloating,
- loose stools or diarrhoea (a mild laxative effect),
- headache,
- allergic skin reactions (rash, itching).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Genologix Milk Thistle Extract 500mg.

You can also report side effects directly to Genologix by completing the side effect report form on our website at https://genologix.co.za/adr-form-page/, or by contacting us on 087 094 0594, WhatsApp 060 532 8317 or info@genologix.co.za.

5. How to store Genologix Milk Thistle Extract 500mg

Store all medicines out of reach of children.

- Store in a cool, dry place at or below 25 °C.
- Protect from light and moisture.
- Keep the capsules in the original pouch. Reseal the pouch tightly after each use.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the pouch.
- Do not use Genologix Milk Thistle Extract 500mg if the pouch seal is broken or the capsules look damaged.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Genologix Milk Thistle Extract 500mg contains

The active substance is a dry extract of milk thistle seed (*Silybum marianum* (L.) Gaertn., fructus), standardised to 80% silymarin.

Active ingredient	Per capsule	Per daily dose (2 capsules)
Milk thistle extract [*Silybum marianum* seed], standardised to 80% silymarin	250 mg	500 mg
providing silymarin	200 mg	400 mg
providing silybin + isosilybin	75 mg	150 mg

The other ingredients are microcrystalline cellulose and hypromellose (the vegan capsule shell).

Microcrystalline cellulose is a plant fibre used as a filler. It makes sure that every capsule contains the correct amount of the active ingredient. These ingredients are not active ingredients. They are only used to help us make the capsules accurately and consistently.

What Genologix Milk Thistle Extract 500mg looks like and contents of the pack

Clear, hard vegan (hypromellose) capsules filled with a light yellow to yellow-brown powder.

The powder in the capsules comes from natural plant material, so its colour can vary from batch to batch. It may be lighter or darker. This is normal. It is caused by natural factors such as soil conditions, rainfall and the time of harvest. It does not affect the quality of the product.

Genologix Milk Thistle Extract 500mg is available in two pack sizes: 60 capsules (30 daily doses) and 240 capsules (120 daily doses). Both are packed in a resealable, laminated, light-protective pouch.

Holder of Certificate of Registration

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Registration number

Not applicable. Unregistered complementary medicine, Act 101/1965.

Access to the corresponding Professional Information

The Professional Information for Genologix Milk Thistle Extract 500mg is available on request from Genologix on 087 094 0594 or info@genologix.co.za. Address your correspondence for the attention of the Responsible Pharmacist.