

PROFESSIONAL INFORMATION
NATIVA COMPLEX® LIVER SUPPORT

SCHEDULING STATUS

[S0]

PROPRIETARY NAME AND DOSAGE FORM
NATIVA COMPLEX® LIVER SUPPORT (capsule)

COMPOSITION

Active Ingredients	per capsule	Per 2 capsules (maximum daily dose)
<i>Silybum marianum</i> (Milk Thistle) [seed, extract standardized to 80 % silymarin]	210 mg	420 mg
L-Methionine	110,28 mg	220,56 mg
Selenium (selenium amino acid chelate)	51 µg	102 µg
<i>Vitis vinifera</i> (Grape seed) [seed, extract standardized to 95 % proanthocyanidins]	10 mg	20 mg
<i>Curcuma longa</i> (Turmeric) [rhizome, extract standardized to 95 % curcumin]	10 mg	20 mg

Excipients: Pirosil; Magnesium stearate; Microcrystalline cellulose.
Nativa Complex® Liver Support is sugar free.

CATEGORY AND CLASS

D.33.7 Complementary Medicines: Discipline-Specific Traditional Claims – Combination Product.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Milk Thistle

Milk thistle constituents such as silymarin have hepatoprotective effects due to their antioxidant and free radical-scavenging actions.

L-Methionine

L-methionine is an amino acid that enhances synthesis of glutathione. It is also used as an adjunct in the treatment of liver disorders.

Selenium

Selenium is part of the glutathione peroxidase enzyme system, which protects intracellular structures against oxidative damage.

Grape seed

Grape seed proanthocyanidins provides protection against reactive oxygen species which cause free radical-induced lipid peroxidation and DNA damage.

Turmeric

Curcumin provides protection against reactive oxygen species and phenolic oxidants.

Pharmacokinetic properties

Milk Thistle

After oral absorption of milk thistle, its constituents can be found in plasma. Silymarin flavonolignans undergo rapid first-pass conjugation and biliary excretion. It is also partially excreted in the urine.

L-Methionine

Methionine is absorbed from the gastrointestinal tract and metabolized in the liver to S-adenosylmethionine and then homocysteine. Homocysteine is then, either remethylated to methionine or forms taurine and cysteine. Methionine is excreted in the urine.

Selenium

Selenium compounds are absorbed in the gastrointestinal tract and stored in red blood cells, the liver, spleen, heart and nails. It is converted to its metabolically active forms in tissues. Selenium is excreted in the urine.

Grape seed

Proanthocyanidins and flavonoids from grape seed extract are absorbed and distributed into serum. The flavonoids are metabolised by intestinal flora and are excreted in the urine.

Turmeric

After absorption, curcumin is present in the plasma as glucuronide and sulfate conjugates. Curcumin is excreted in both the urine and faeces.

INDICATIONS

Nativa Complex® Liver Support is indicated for the support of liver health and function, the relief of indigestion and digestive complaints originating from the liver and for antioxidant protection of the liver.

CONTRAINDICATIONS

Hypersensitivity to Asteraceae (Daisy) family or any of the ingredients of Nativa Complex® Liver Support (see **COMPOSITION**).

Nativa Complex® Liver Support contains L-methionine, which is contraindicated for patients with acidosis, hyperuricemia or hyperuricosuria, uric acid- or cysteine containing renal calculi or metabolic disorders like oxalosis, homocystinuria or hypermethioninaemia.

WARNINGS AND SPECIAL PRECAUTIONS

Do not use if known hypersensitivity or allergy exists to the Asteraceae (Daisy) family or to any of the ingredients. If in doubt, consult your medical practitioner. The ingredients in Nativa Complex® Liver Support may interact with other medications (see **INTERACTIONS**).

Consult a healthcare practitioner prior to use if you have existing liver damage or liver disease. Consult a healthcare practitioner before use if you have acidosis, atherosclerosis or high levels of homocysteine in the blood as Nativa Complex® Liver Support contains L-methionine.

Consult a healthcare practitioner before use if you suffer from bile duct obstruction, cholangitis, gallstones, stomach ulcers, excess stomach acid or any other biliary or liver diseases as Nativa Complex® Liver Support contains turmeric .

Consult a healthcare practitioner before use if you have a history of non-melanoma skin cancer as Nativa Complex® Liver Support contains selenium.

This product is not suitable for children under the age of 18.
Porphyria: Safety has not been established.

INTERACTIONS

If you are taking blood thinners or antidiabetic drugs consult your doctor, pharmacist or other healthcare professional before use.

HUMAN REPRODUCTION

Pregnancy

It is not advisable to use Nativa Complex® Liver Support while you are pregnant due to the lack of relevant information.

Women of Childbearing Potential

There are no known restrictions for use of Nativa Complex® Liver Support in women of childbearing age.

Lactation

It is not advisable to use Nativa Complex® Liver Support while you are breastfeeding due to the lack of relevant information.

Fertility

There are no known effects of Nativa Complex® Liver Support on fertility.

DOSAGE AND DIRECTIONS FOR USE

Dosage

Do not exceed the recommended daily dosage.

Adults 18 years and older:

Take one (1) capsule once or twice daily.

Directions for use

Take one (1) capsule once or twice daily, after a meal, with a glass of water.

SIDE EFFECTS

If you experience any side effects or sensitivity towards any of the ingredients, discontinue use.

If symptoms persist, or if any adverse reactions occur, consult a medical practitioner.

Side effects may include, but are not limited to:

Nervous system disorders:

Frequency unknown: headache, drowsiness, dizziness, irritability

Gastrointestinal disorders:

Frequency unknown: nausea, vomiting, diarrhoea, dyspepsia, abdominal discomfort, constipation

Skin and subcutaneous tissue disorders:

Frequency unknown: hypersensitivity reaction (skin rash, urticaria, anaphylaxis)

Product issues

No product issues are available on Nativa Complex® Liver Support

Post-marketing data

No side effects of Nativa Complex® Liver Support have been reported post-marketing.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms of Overdosage

See **SIDE EFFECTS**.

Do not exceed the recommended daily dosage.

Treatment of Overdosage

If an accidental overdose occurs, consult a medical practitioner.

Treatment is symptomatic and supportive.

IDENTIFICATION

Size 0 green-white gelatine capsule.

PRESENTATION

Blister pack with 1 strip of 10 capsules each, in a unit carton, with a package insert.

White plastic bottle with green flip-top cap, containing 30 capsules, with a leaflet, in a unit carton.

White plastic bottle with green flip-top cap, containing 60 capsules, with a leaflet, in a unit carton.

STORAGE INSTRUCTIONS

- Store in a cool, dry place at or below 25 °C
- Protect from light and moisture.
- Keep in original packaging until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the blister pack, bottle and unit carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

To be allocated

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Nativa (Pty) Ltd
260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa
Tel: +27 (0) 12 664 7110
Customer care line: 0860 628 482
Email: health@nativa.co.za
Website: www.nativa.co.za

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

To be allocated

DATE OF REGISTRATION

To be allocated

COMPLEMENTARY MEDICINE

Discipline-Specific Traditional Claims

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