

PATIENT INFORMATION LEAFLET

Scheduling status:

[S0]

NATIVA COMPLEX® GOUT SUPPORT capsule

Boswellia serrata Roxb. Ex Colebr. (Indian frankincense) [resin powder]; *Curcuma longa* L. (turmeric/curcumin) [rhizome Powder]; *Harpagophytum procumbens* (Burch.) DC. ex Meisn. (devil's claw) [root, 4:1 extract providing 200 mg of dried herb equivalent]; bromelain; papain; ascorbic acid (vitamin C); *Pinus pinaster* spp. (Pine) [bark, 4:1 extract providing 100 mg of dried herb equivalent]; *Vitis vinifera* L. (grape seed) [seed, as extract standardized to 95 % proanthocyanidins].

Sugar and preservative free.

- Complementary Medicine: D.33.7 Discipline Specific Traditional Claims – Combination Product.
- A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

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

Nativa Complex® Gout Support is available without a doctor's prescription. Nevertheless, you still need to use Nativa Complex® Gout Support carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Nativa Complex® Gout Support with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

WHAT IS IN THIS LEAFLET

1. What Nativa Complex® Gout Support is and what it is used for
2. What you need to know before you take Nativa Complex® Gout Support
3. How to take Nativa Complex® Gout Support
4. Possible side effects
5. How to store Nativa Complex® Gout Support
6. Contents of the pack and other information

1. What Nativa Complex® Gout Support is and what it is used for

Nativa Complex® Gout Support capsules is a herbal supplement that can provide the body with anti-inflammatory and antioxidant support for relief of symptoms associated with gout. For a diagnosis or if symptoms persist, consult a medical practitioner.
Efficacy of support may vary between users.

2. What you need to know before you take Nativa Complex® Gout Support

Do not take Nativa Complex® Gout Support:

- If you have an allergy to latex or fruits (e.g., avocado, banana, chestnut, passion fruit, fig, melon, mango, kiwi, pineapple, peach and tomato) as Nativa Complex® Gout Support contains papain.
- If you have a hypersensitivity (e.g. allergy) towards bromelain, if a reaction occurs discontinue use and consult a relevant healthcare provider.
- If you are hypersensitive (allergic) to any of the ingredients of Nativa Complex® Gout Support (listed in section 6 **Contents of pack and other information**).
- If you are pregnant or breastfeeding as Nativa Complex® Gout Support contains turmeric, devil's claw, grape seed, bromelain and papain (see **Pregnancy and Breastfeeding**).
- Not suitable for children under 18 years of age as Nativa Complex® Gout Support contains papain and bromelain.
- If you are taking any chronic medication do not use this product without consulting your medical practitioner.

Warnings and precautions

- Special care should be taken with Nativa Complex® Gout Support. Consult a healthcare provider before use if you have:
 - o Gallstones;
 - o bile duct obstructions;
 - o stomach lesions/ulcers; or
 - o excess stomach acid.
- Consult a healthcare provider before use if you are taking blood thinners, diabetic medication or immune suppressant medication (see **Other medicines and Nativa Complex® Gout Support**).
- If you have malabsorption or other gastrointestinal tract ailments or are having surgery use the product with caution as Nativa Complex® Gout Support contains bromelain and papain.
- Consult a relevant healthcare provider for prolonged use.
- Discontinue use at least 2 weeks before elective surgical procedures as Nativa Complex® Gout Support contains pine.
- Consult a relevant healthcare provider if symptoms persist or worsen.
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.
- Products containing herbal ingredients may interact with some medication.

Porphyria: Safety has not been established.

Tell your doctor if you are not sure about any of the above.

Other medicines and Nativa Complex® Gout Support

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicines.

Consult your doctor, pharmacist or healthcare provider before use if you are taking:

- Blood thinners (anticoagulant - or antiplatelet medication) e.g. warfarin, as some of the ingredients may have a blood thinning effect increasing the risk of bleeding;
- hormonal contraception, as the vitamin C in Nativa Complex® Gout Support may increase levels of oestrogens in cases where supplements are taken when a vitamin C deficiency exists;
- fluphenazine, as the vitamin C in Nativa Complex® Gout Support may decrease levels;
- antidiabetic medication, as concomitant use with turmeric and pine may increase the risk of hypoglycaemia;
- sulfasalazine, as the turmeric in Nativa Complex® Gout Support may increase the effects and adverse effects; or
- immunosuppressant medication, as the pine in Nativa Complex® Gout Support may decrease the effectiveness.

Taking Nativa Complex® Gout Support with food, drink and alcohol

There is no known interaction between contents of Nativa Complex® Gout Support and food, drink and alcohol.

Pregnancy, breastfeeding and fertility

Do not use Nativa Complex® Gout Support if you are pregnant or breastfeeding as safety has not been established.

Devil's claw and papain are specifically contraindicated, therefore this product should not be used if you are pregnant.

Driving and using machinery

Nativa Complex® Gout Support should not affect your ability to drive or use machinery. However, if you think you are affected you should not drive or operate machinery until you feel better.

It is not always possible to predict to what extent Nativa Complex® Gout Support may interfere with your daily activities. Ensure that you do not engage in the above activities until you are aware of the measure to which Nativa Complex® Gout Support affects you.

3. How to take Nativa Complex® Gout Support

Do not share medicines with any other person.

Always take Nativa Complex® Gout Support exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are unsure.

The usual dose for adults 18 years and older is:

One (1) to two (2) capsules per day, with a glass of water, after a meal.

If you take more Nativa Complex® Gout Support than you should

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

If you forget to take Nativa Complex® Gout Support

Take your missed dose when you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Nativa Complex® Gout Support

If you are taking the dose as indicated, it is unlikely that there should be withdrawal effects when you stop using this medication.

4. Possible side effects

Nativa Complex® Gout Support can have side effects.

Not all side effects reported for Nativa Complex® Gout Support are included in this leaflet. Should your general health worsen while or if you experience any untoward effects while taking Nativa Complex® Gout Support, please consult your healthcare provider for advice.

If any of the following or other side effects occur, stop taking this product and consult your doctor or pharmacist or go to the casualty department at your nearest hospital:

Allergic reactions such as: skin rashes, hives (skin bumps), itchiness, swelling of the face, lips mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to Nativa Complex® Gout Support. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice any of the following:

Frequency unknown:

- Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria (hives), skin rash and itching.
- Headache and vertigo (sensation of feeling off balance).
- Abdominal pain, flatulence, dry mouth, gastrointestinal upsets including diarrhoea, heartburn, nausea and vomiting.
- Oedema (a build-up of fluid causing swelling) of the foot and general weakness.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the

“6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of Nativa Complex® Gout Support.

5. How to store Nativa Complex® Gout Support

- Store all medicines out of reach of children.
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Do not refrigerate.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What Nativa Complex® Gout Support contains

Active ingredients	Per capsule	Per maximum daily dose (2 capsules)	% NRV* per maximum daily dose (2 capsules)
<i>Boswellia serrata</i> Roxb. Ex Colebr. (Indian frankincense) [resin powder]	50 mg	100 mg	*
<i>Curcuma longa</i> L. (Turmeric/Curcumin) [rhizome powder]	50 mg	100 mg	*
<i>Harpagophytum procumbens</i> (Burch.) DC. ex Meisn. (Devil's claw) [root, 4:1 extract providing 200 mg of dried herb equivalent]	50 mg	100 mg	*
Bromelain Providing:	100 mg 120000 FCC PU**	200 mg 240000 FCC PU**	*
Papain Providing:	50 mg 300000 FCC PU**	100 mg 600000 FCC PU**	*
Ascorbic acid (Vitamin C)	30 mg	60 mg	60 %
<i>Pinus pinaster</i> spp. (Pine) [bark, 4:1 extract providing 100 mg of dried herb equivalent]	25 mg	50 mg	*
<i>Vitis vinifera</i> L. (Grape seed) [seed, as extract standardised to 95 % proanthocyanidins]	25 mg	50 mg	*

*Nutrient reference values for adults and children older than 4 years.

**NRV not established.

**Food Chemical Codex Papain Unit.

The other ingredients or excipients are: colloidal silicon dioxide gelatine capsule (capsule constituents: bovine gelatine, colourants, titanium dioxide), magnesium stearate and tapioca starch.

Nativa Complex® Gout Support is sugar and preservative free.

What Nativa Complex® Gout Support looks like and contents of the pack

Nativa Complex® Gout Support are brown capsules, available in a white plastic container with a brown flip-top cap.

It contains 60 capsules and includes a patient information leaflet in a printed unit carton.

Holder of 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

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Date of registration

To be allocated

Registration number

To be allocated

Professional Information

The Nativa Complex® Gout Support Professional Information may be obtained from the Nativa website

(www.nativa.co.za).