

PATIENT INFORMATION LEAFLET

Scheduling status:

[S0]

NATIVA COMPLEX® DIGESTIVE SUPPORT capsule

Rhamnus purshiana DC. (cascara sagrada) [bark powder]; *Zingiber officinale* Rosc. (ginger) [root powder]; *Allium sativum* L. (garlic) [bulb, 4:1 extract providing 100 mg of dried herb equivalent]; *Foeniculum vulgare* Mill. (fennel) [seed powder]; papain enzyme; bromelain blend; inulin (prebiotic); pectin; probiotic blend.

Sugar free and preservative free.

- Complementary Medicines: 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 the entirety of this leaflet carefully because it contains important information for you.

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

- Keep this leaflet. You may need to read it again.
- Do not share Nativa Complex® Digestive 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® Digestive Support is and what it is used for
2. What you need to know before you take Nativa Complex® Digestive Support
3. How to take Nativa Complex® Digestive Support
4. Possible side effects
5. How to store Nativa Complex® Digestive Support
6. Contents of the pack and other information

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

Nativa Complex® Digestive Support is a health supplement intended to maintain gut health and comfort, aiding in digestion and nutrient absorption and supports a healthy digestive balance. The ingredients can assist the body with support and functioning of the digestive system supporting regular bowel movement and assisting in the countering of constipation.

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

Do not take Nativa Complex® Digestive 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® Digestive Support contains papain. Consult a relevant healthcare provider prior to use.
- Hypersensitivity (e.g. allergy) towards bromelain has been known to occur. In such cases discontinue use and consult a relevant healthcare provider.
- If you are hypersensitive (allergic) to fennel or plants of the *Apiaceae* (*Umbelliferae*) family or to bromelain-latex or to plants of the *Bromeliaceae* (pineapple) family.
- If you are hypersensitive (allergic) to any other ingredient of Nativa Complex® Digestive Support (listed in section 6 **Contents of pack and other information**).
- If you have short bowel syndrome, blockage (intestinal obstruction) or narrowing (stenosis) of the gastrointestinal tract or bowel.
- If you have atony (paralysis or lack of muscle tone in the bowel) of the bowel.
- If you have inflammatory colon disease such as Crohn's disease or ulcerative colitis.
- If you have symptoms of appendicitis: abdominal pain, nausea, fever or vomiting.
- If you have ulcers or unexplained abdominal pain.
- If you are severely dehydrated and/or have an electrolyte imbalance.
- If you are pregnant or breastfeeding (see section on **Pregnancy, breastfeeding and fertility**).

Warnings and precautions

Ask your doctor if you are not sure about any of the below.

- Special care should be taken with Nativa Complex® Digestive Support. Consult a healthcare provider before use if you have:
 - o Bleeding disorders;
 - o diabetes;
 - o low blood pressure;
 - o kidney disorder;
 - o faecal impaction;
 - o abdominal pain;
 - o nausea;
 - o vomiting; or
 - o fever.
- If you have malabsorption or other gastrointestinal tract ailments or are having surgery use the product with caution as Nativa Complex® Digestive Support contains bromelain and papain.
- If you have gallstones, bile duct obstructions, stomach lesions/ulcers or excess stomach acid use the product with caution as it contains bromelain.
- Discontinue use 2 weeks before elective surgical procedures due to the antiplatelet and blood glucose effects of Nativa Complex® Digestive Support.
- 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.

Porphyrria: Safety has not been established.

Other medicines with Nativa Complex® Digestive Support

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

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

- Anticoagulants (blood-thinners) e.g., warfarin. papain, bromelain, cascara sagrada, ginger, garlic and fennel may have additive blood-thinning effects;
- antidiabetic medication. Ginger and garlic may decrease blood glucose levels;
- antihypertensive drugs. Ginger and garlic may lower blood pressure further;
- corticosteroids and diuretics (water tablet). Taking cascara sagrada with these medications may increase the risk of low blood potassium levels;
- digoxin (for heart failure or irregular heartbeat). Cascara sagrada and pectin may influence the blood levels of digoxin;
- immunosuppressants (e.g., methotrexate used for rheumatoid arthritis or other autoimmune conditions). Taking garlic and probiotics with these medications may increase the risk of infection; or
- other oral medications, including antibiotics (specifically amoxycillin [e.g., Amoxil®], ciprofloxacin [e.g., Ciprobay®] and tetracyclines [e.g., Doxycycline®]). Absorption of some medications may be influenced and, also, antibiotics may destroy the prebiotics in this product. Take Nativa Complex® Digestive Support two (2) hours before or two (2) hours after other medications.

Taking Nativa Complex® Digestive Support with food and drink and alcohol

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

Pregnancy, breastfeeding and fertility

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

Driving and using machinery

Nativa Complex® Digestive Support should not affect your ability to drive or operate 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® Digestive 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® Digestive Support affects you.

3. How to take Nativa Complex® Digestive Support

Do not share medicines with any other person.

Always take Nativa Complex® Digestive Support exactly as described in this leaflet or as your healthcare provider has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults 18 years and older:

Take one (1) or two (2) capsules per day, after a meal, with a glass of water.

Reduce dose or stop use if you experience abdominal pain, cramps, spasms and/or diarrhoea.

Take a few hours before or after taking other medications (see **Other medicines with Nativa Complex® Digestive Support**).

If you take more Nativa Complex® Digestive 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® Digestive 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® Digestive 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® Digestive Support can have side effects.

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

Like all medicines, this medicine can cause side effects although not everybody gets them.

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® Digestive Support. You may need urgent medical attention or hospitalisation.

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

Frequency unknown:

- Abdominal discomfort, belching, constipation, diarrhea, dyspepsia (difficulty in swallowing), heartburn, flatulence (gassiness), nausea, vomiting.

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® Digestive Support.

5. How to store Nativa Complex® Digestive 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® Digestive Support contains

Active Ingredients	Per capsule	Per 2 capsules (maximum daily dose)
<i>Rhamnus purshiana</i> DC. (Cascara sagrada) [bark powder]	50 mg	100 mg
<i>Zingiber officinale</i> Rosc. (Ginger) [root powder]	50 mg	100 mg
<i>Allium sativum</i> L. (Garlic) [bulb, 4:1 extract providing 100 mg of dried herb equivalent]	25 mg	50 mg
<i>Foeniculum vulgare</i> Mill. (Fennel) [seed powder]	20 mg	40 mg
Papain providing:	50 mg 300000 FCC PU**	100 mg 600000 FCC PU**
Bromelain providing:	50 mg 60000 FCC PU**	100 mg 120000 FCC PU**
Inulin (prebiotic)	50 mg	100 mg
Pectin	20 mg	40 mg
Probiotic blend providing:	1 billion CFU*	2 billion CFU*
<i>Lactobacillus acidophilus</i>	500 million CFU*	1 billion CFU*
<i>Bifidobacterium longum</i>	167 million CFU*	334 million CFU*
<i>Bifidobacterium bifidum</i>	167 million CFU*	334 million CFU*
<i>Bifidobacterium lactis</i>	166 million CFU*	332 million CFU*

*Colony Forming Unit.

**Food Chemical Codex Papain Unit.

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

Nativa Complex® Digestive Support is sugar and preservative free.

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

Nativa Complex® Digestive Support are light green capsules, available in a white plastic container with a green flip-top cap. It contains 60 capsules and includes a patient information leaflet in a printed unit carton.

Holder of Certificate of Registration

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Date of registration

To be allocated

Registration number

To be allocated

Professional Information

The Nativa Complex® Digestive Support Professional Information may be obtained from the Nativa website (www.nativa.co.za).