

**PATIENT INFORMATION LEAFLET**

**Scheduling status:**

**S0**

**NATIVA COMPLEX® NIGHT capsules**

*Valeriana officinalis* L., (valerian) root extract; magnesium (magnesium oxide).

Sugar free

- Complementary Medicine: Discipline-Specific Traditional Claims – Combination Product
- 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® Night is available without a doctor's prescription. Nevertheless, you still need to use Nativa Complex® Night carefully to get the best results from it.

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

**1. What Nativa Complex® Night is and what it is used for**

Nativa Complex® Night is a herbal medicine indicated for the relief of sleeping difficulties, mild stress and mild nervousness (nervous excitation). Nativa Complex® Night also contains magnesium to support the normal functioning of the nervous system.

**2. What you need to know before you take Nativa Complex® Night**

**Do not take Nativa Complex® Night:**

- If you are hypersensitive (allergic) to any of the ingredients of Nativa Complex® Night (listed in section 6).

**Warnings and precautions**

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

- Consult a healthcare provider if symptoms persist or worsen after 2 weeks (see **How to take Nativa Complex® Night**).
- Avoid taking with alcohol or products that cause drowsiness (see **Other medicines and Nativa Complex® Night**).

**Porphyria:** Safety has not been established.

**Other medicines and Nativa Complex® Night**

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:

- Antibiotics (used to treat infections), as the magnesium in Nativa Complex® Night may reduce their absorption. You should take all oral antibiotics at least two (2) hours before, or four (4) hours after Nativa Complex® Night or similar supplements.
- Avoid taking Nativa Complex® Night with alcohol, herbal and health supplements or medications that increase drowsiness as the combination may increase the sedative effects.

**Taking Nativa Complex® Night with food and drink**

You should take Nativa Complex® Night with a glass of water. Taking Nativa Complex® Night with or without food has no influence on the effect.

**Pregnancy and Breastfeeding**

It is not advisable to take Nativa Complex® Night while you are pregnant or breastfeeding as safety has not been established. If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor or pharmacist or other healthcare provider for advice before taking this medication.

**Driving and using machinery**

Nativa Complex® Night can cause drowsiness in some people. This would affect your ability to drive or use machinery. If you think you are affected you should not drive or operate machinery until you feel better.

**3. How to take Nativa Complex® Night**

Do not share medicines with any other person.

Always take Nativa Complex® Night 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 and children 12 years and older:*

*For relief of sleeping difficulties:* Take one (1) to two (2) capsules half an hour to one (1) hour before bedtime with a glass of water. One (1) to two (2) additional capsules can be taken earlier in the evening if necessary.

*For relief of mild nervousness:* Take one (1) to two (2) capsules two (2) times per day with a glass of water.

The efficacy of Nativa Complex® Night is gradual and is not suitable for immediate (acute) treatment of mild nervous tension or sleeping difficulties. To achieve the optimal effect, continued use over 2 to 4 weeks is recommended. If symptoms persist or worsen after 2 weeks of continued use, consult a doctor or pharmacist.

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

**If you take more Nativa Complex® Night than you should**

At high doses valerian root can cause symptoms such as tiredness, abdominal cramps, chest tightness, light-headedness, shaking hands and dilated pupils, which disappears within 24 hours. If symptoms arise, treatment should be supportive.

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 Nativa Complex® Night**

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® Night**

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® Night can have side effects

Not all side effects reported for Nativa Complex® Night are included in this leaflet. Should your general health worsen while taking this medicine, or if you experience any untoward effects while taking this medicine, 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 inflammation or rash

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

*Frequency unknown:*

- Abdominal discomfort, nausea and stomach cramps.
- Dizziness, drowsiness, mental slowness and headache.

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 **“Adverse Drug Reactions and Quality Problem Reporting Form”**, found online under SAHPRA's publications: [www.sahpracm.org.za](http://www.sahpracm.org.za). By reporting side effects, you can help provide more information on the safety of Nativa Complex® Night.

**5. How to store Nativa Complex® Night**

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store in a dry place at or below 25 °C.
- Protect from light.
- 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® Night contains**

Active Ingredients	Per capsule	Per max daily dose (4 capsules)
<i>Valeriana officinalis</i> L., (valerian) [root, extract 3-6:1 standardised to 0,8 % valerenic acid providing 630 mg of dried root equivalent]	210 mg	840 mg
Magnesium (magnesium oxide)	50 mg	200 mg

The other ingredients are: gelatine capsule (bovine), magnesium stearate, microcrystalline cellulose

Nativa Complex® Night is sugar free.

**What Nativa Complex® Night looks like and contents of the pack**

Nativa Complex® Night are purple, hard gelatine capsules, with a brown powder, available in a white plastic container with a purple flip-top cap. It contains 30 capsules and is packed in a printed unit carton that includes a patient information leaflet.

**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](mailto:health@nativa.co.za)  
Website: [www.nativa.co.za](http://www.nativa.co.za)

**This leaflet was last revised in**

March 2021

**Date of registration**

To be allocated

**Registration number**

To be allocated

**Professional Information**

The Nativa Complex® Night Professional Information may be obtained from the Nativa website ([www.nativa.co.za](http://www.nativa.co.za)).