

PATIENT INFORMATION LEAFLET

Scheduling status:

[S0]

NATIVA COMPLEX® DIABETIC MULTIVITAMIN capsule

Vitamin A acetate (Vitamin A); Thiamine hydrochloride (Vitamin B1); Riboflavin (Vitamin B2); Nicotinamide (Vitamin B3); Calcium-D pantothenate (Vitamin B5); Pyridoxine hydrochloride (Vitamin B6); Folic acid (Vitamin B9); Cyanocobalamin (Vitamin B12); D-biotin (Vitamin H); Ascorbic acid (Vitamin C); Cholecalciferol (Vitamin D3); Tocopheryl acetate (Vitamin E); Magnesium oxide (Magnesium), Zinc amino acid chelate (Zinc); Ferrous fumarate (Iron); Chromium polynicotinate (Chromium); Selenium amino acid chelate (Selenium).

Sugar and preservative free

- D.34.12 Health Supplements – Multiple substance formulation.
- 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® Diabetic Multivitamin is available without a doctor's prescription. Nevertheless, you still need to use Nativa Complex® Diabetic Multivitamin carefully to get the best results from it.

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

WHAT IS IN THIS LEAFLET

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

1. What Nativa Complex® Diabetic Multivitamin is and what it is used for

Nativa Complex® Diabetic Multivitamin is a health supplement indicated for the support of overall health and well-being. Nativa Complex® Diabetic Multivitamin is specifically formulated for individuals with diabetes.

2. What you need to know before you take Nativa Complex® Diabetic Multivitamin

Do not take Nativa Complex® Diabetic Multivitamin:

- If you are hypersensitive (allergic) to any of the ingredients of Nativa Complex® Diabetic Multivitamin (listed in section **6 Contents of pack and other information**).
- If you suffer from liver disease or have peptic ulcer disease as Nativa Complex® Diabetic Multivitamin contains nicotinamide.
- If you have cobalamin or cobalt hypersensitivity as Nativa Complex® Diabetic Multivitamin contains vitamin B12.
- If you are taking retinoids as Nativa Complex® Diabetic Multivitamin contains vitamin A (see **Other medicines and Nativa Complex® Diabetic Multivitamin**).

Warnings and precautions

- Special care should be taken with Nativa Complex® Diabetic Multivitamin. Consult a healthcare provider before use if you have:
 - o Bleeding disorders;
 - o a history of oxalate kidney stones; or
 - o a history of non-melanoma skin cancer.
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.

Porphyria: Safety has not been established.

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

Other medicines with Nativa Complex® Diabetic Multivitamin

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:

- Blood thinners (anticoagulant - or anti-platelet medication) e.g. warfarin, as some of the ingredients may have a blood thinning effect increasing the risk of bleeding;
- retinoid medication as it could have additive toxic effects when taken with vitamin A supplements, avoid vitamin A supplements with retinoid medication; or
- antibiotics (used to treat infections), as some of the ingredients in Nativa Complex® Diabetic Multivitamin may reduce their absorption. You should take all oral antibiotics at least two (2) hours before, or four (4) hours after Nativa Complex® Diabetic Multivitamin or similar supplements.

Taking Nativa Complex® Diabetic Multivitamin with food and alcohol

There is no known interaction between contents of Nativa Complex® Diabetic Multivitamin and food and alcohol.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your medical practitioner for advice before using Nativa Complex® Diabetic Multivitamin.

Driving and using machinery

Nativa Complex® Diabetic Multivitamin 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® Diabetic Multivitamin 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® Diabetic Multivitamin affects you.

3. How to take Nativa Complex® Diabetic Multivitamin

Do not share medicines with any other person.

Always take Nativa Complex® Diabetic Multivitamin 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.

The usual dose for adults 18 years and older is:

Take one (1) capsule per day, after breakfast, with a glass of water.

Children:

Use in children under the guidance of a relevant healthcare practitioner.

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

If you take more Nativa Complex® Diabetic Multivitamin 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® Diabetic Multivitamin

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® Diabetic Multivitamin

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® Diabetic Multivitamin can have side effects.

Not all side effects reported for Nativa Complex® Diabetic Multivitamin 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® Diabetic Multivitamin, please consult your healthcare practitioner 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® Diabetic Multivitamin. You may need urgent medical attention or hospitalisation.

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

Frequency unknown:

- Abdominal discomfort, constipation, decreased appetite, diarrhea, difficulty swallowing (dysphagia), gas (flatulence), heartburn, 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® Diabetic Multivitamin.

5. How to store Nativa Complex® Diabetic Multivitamin

- 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® Diabetic Multivitamin contains

Active ingredient	Per capsule	%NRV* per capsule (maximum daily dosage)
Vitamin A acetate (Vitamin A)	3950 IU (1196,97 µg RAE*)	132 %
Thiamine hydrochloride (Vitamin B1)	5,61 mg	468 %
Riboflavin (Vitamin B2)	1,6 mg	123 %
Nicotinamide (Vitamin B3)	18 mg	113 %
Calcium-D pantothenate (Vitamin B5)	6,56 mg	131 %
Pyridoxine hydrochloride (Vitamin B6)	30,38 mg	1787 %
Folic acid (Vitamin B9)	500 µg	125 %
Cyanocobalamin (Vitamin B12)	25 µg	1042 %
D-biotin (Vitamin H)	100 µg	333 %
Ascorbic acid (Vitamin C)	150 mg	150 %
Cholecalciferol (Vitamin D3)	480 IU (12 µg)	80 %
Tocopheryl acetate (Vitamin E)	28,31 IU (19 mg TE***)	189 %
Magnesium oxide providing Magnesium (elemental)	250 mg 150,77 mg	38 %
Zinc AAC** providing Zinc (elemental)	75 mg 15 mg	136 %
Ferrous fumarate providing Iron (elemental)	30,42 mg 9,97 mg	56 %
Chromium polynicotinate providing Chromium (elemental)	1608,97 mg 200 µg	571 %
Selenium AAC ** providing Selenium (elemental)	3 mg 60 µg	109 %

*Nutrient Reference Values for adults and children older than 4 years.

*Retinol activity equivalents.

**Amino Acid Chelate.

***D-alpha-Tocopherol Equivalents.

The other ingredients or excipients are: gelatine capsule (capsule constituents: bovine gelatine, colourants, titanium dioxide), microcrystalline cellulose.

Nativa Complex® Diabetic Multivitamin is sugar and preservative free.

What Nativa Complex® Diabetic Multivitamin looks like and contents of the pack

Nativa Complex® Diabetic Multivitamin are white capsules, available in a white plastic container with blue flip-top cap. It contains 30 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

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Professional Information

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