

PATIENT INFORMATION LEAFLET

Scheduling status:

[S0]

NATIVA COMPLEX® MULTIVITAMIN FOR WOMEN capsule

Calcium carbonate (Calcium); Ascorbic acid (Vitamin C); Magnesium oxide (Magnesium); *Polygonum Cuspidatum* (Giant Knotweed) [root, extract standardised to 50 % Resveratrol]; Pyridoxine hydrochloride (Vitamin B6); Tocopheryl acetate (Vitamin E); Nicotinamide (Vitamin B3); Zinc amino acid chelate (Zinc); Ferrous fumarate (Iron); Calcium-D pantothenate (Vitamin B5); Riboflavin (Vitamin B2); Thiamine hydrochloride (Vitamin B1); Manganese sulfate (Manganese); Copper amino acid chelate (Copper); Beta-carotene (Vitamin A); Lycopene; Folic acid (Vitamin B9); D-biotin (Vitamin H); Selenium amino acid chelate (Selenium); Chromium polynicotinate (Chromium); Cyanocobalamin (Vitamin B12); Cholecalciferol (Vitamin D3).

Sugar free

- D.34.12 Complementary Medicine: Health Supplements – Multiple substance formulation.
- Health Supplements are intended only to complement health or supplement the diet. 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® Multivitamin for Women is available without a doctor's prescription. Nevertheless, you still need to use Nativa Complex® Multivitamin for Women carefully to get the best results from it.

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

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

Nativa Complex® Multivitamin for Women is a general daily supplement specifically formulated for women. It can assist the body with antioxidant -, immune function - and energy support. The formula contains iron, folic acid, vitamin B6, resveratrol and lycopene in quantities targeted to support health specific to women.

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

Do not take Nativa Complex® Multivitamin for Women:

- If you are hypersensitive (allergic) to any of the ingredients of Nativa Complex® Multivitamin for Women (listed in section 6 **Contents of pack and other information**).
- If you are pregnant or breastfeeding as Nativa Complex® Multivitamin for Women contains resveratrol and vitamin A (see **Pregnancy and Breastfeeding**).
- If you suffer from liver disease or have peptic ulcer disease as Nativa Complex® Multivitamin for Women contains nicotinamide.
- If you have cobalamin or cobalt hypersensitivity as Nativa Complex® Multivitamin for Women contains vitamin B12.
- If you are taking retinoids as Nativa Complex® Multivitamin for Women contains vitamin A (see **Other medicines and Nativa Complex® Multivitamin for Women**)
- If you are taking any chronic medication do not use this product without consulting your medical practitioner.

Not suitable for children as Nativa Complex® Multivitamin for Women contains resveratrol.

Warnings and precautions

- Consult a healthcare provider before use if you have:
 - Bleeding disorders;
 - a history of oxalate kidney stones;
 - any hormone sensitive conditions;
 - diagnosed or suspected prostate cancer; or
 - a history of non-melanoma skin cancer.
- 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® Multivitamin for Women

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

Take Nativa Complex® Multivitamin for Women a few hours before or after other medication (see **How to take Nativa Complex® Multivitamin for Women**).

Taking Nativa Complex® Multivitamin for Women with food and drink

You should take Nativa Complex® Multivitamin for Women after a meal with a glass of water.

There is no known interaction between contents of Nativa Complex® Multivitamin for Women and food and drink.

Pregnancy and Breastfeeding

Do not use Nativa Complex® Multivitamin for Women if you are pregnant or breastfeeding as safety has not been established.

Driving and using machinery

Nativa Complex® Multivitamin for Women 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.

3. How to take Nativa Complex® Multivitamin for Women

Do not share medicines with any other person.

Always take Nativa Complex® Multivitamin for Women 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:

Two (2) capsules per day, with a glass of water, after a meal.

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

If you take more Nativa Complex® Multivitamin for Women 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® Multivitamin for Women

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® Multivitamin for Women

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® Multivitamin for Women can have side effects.

Not all side effects reported for Nativa Complex® Multivitamin for Women 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 as 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.

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.
- Abdominal discomfort, - pain, - cramps and - fullness, constipation, diarrhoea, dyspepsia, heartburn, nausea, vomiting, halitosis, belching, flatulence, dry mouth.

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://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf. By reporting side effects, you can help provide more information on the safety of Nativa Complex® Multivitamin for Women.

5. How to store Nativa Complex® Multivitamin for Women

- 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® Multivitamin for Women contains

Active Ingredients	Per capsule	Per maximum daily dose (2 capsules)	% NRV* per 2 capsules (maximum daily dose)
Beta-carotene (Vitamin A)	1330 IU (399,4 µg RAE****)	2660 IU (798,8 µg RAE****)	89 %
Thiamine hydrochloride (Vitamin B1)	3,5 mg	7 mg	583 %
Riboflavin (Vitamin B2)	4 mg	8 mg	615 %
Nicotinamide (Vitamin B3)	9 mg	18 mg	113 %
Calcium-D pantothenate (Vitamin B5)	5 mg	10 mg	200 %
Pyridoxine hydrochloride (Vitamin B6)	12,5 mg	25 mg	1471 %
Folic acid (Vitamin B9)	200 µg	400 µg	100 %
Cyanocobalamin (Vitamin B12)	2,5 µg	5 µg	208 %
Ascorbic acid (Vitamin C)	50 mg	100 mg	100 %
Cholecalciferol (Vitamin D3)	100 IU (2,5 µg)	200 IU (5 µg)	33 %
Tocopheryl acetate (Vitamin E)	14,9 IU (10 mg a-TE**)	29,8 IU (20 mg a-TE**)	133 %
Calcium carbonate providing Calcium (elemental)	150 mg 60 mg	300 mg 120 mg	9 %
Chromium polynicotinate providing Chromium (elemental)	250 µg 30 µg	500 µg 60 µg	171 %
Copper AAC*** providing Copper (elemental)	5 mg 0,5 mg	10 mg 1 mg	111 %
D-biotin (Vitamin H)	150 µg	300 µg	1000 %
Ferrous fumarate providing Iron (elemental)	21,3 mg 7 mg	42,6 mg 14 mg	78 %
Magnesium oxide providing Magnesium (elemental)	50 mg 30 mg	100 mg 60 mg	14 %
Manganese sulfate providing Manganese (elemental)	1,6 mg 0,5 mg	3,2 mg 1 mg	44 %
Selenium AAC*** providing Selenium (elemental)	2,5 mg 50 µg	5 mg 100 µg	182 %
Zinc AAC*** providing Zinc (elemental)	37,5 mg 7,5 mg	75 mg 15 mg	136 %
Lycopene	375 µg	750 µg	*
<i>Polygonum Cuspidatum</i> (Giant Knotweed) [root, extract standardised to 50 % Resveratrol]	20 mg	40 mg	*

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

* NRV not established.

** D-alpha-Tocopherol Equivalents.

*** Amino Acid Chelate.

**** Retinol Activity Equivalents.

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

Nativa Complex® Multivitamin for Women is sugar free.

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

Nativa Complex® Multivitamin for Women are light pink capsules, available in a white plastic container with a pink 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 Dock 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

This leaflet was last revised in

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Date of registration

To be allocated

Registration number

To be allocated

Professional Information

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