

## PROFESSIONAL INFORMATION

### NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS

#### SCHEDULING STATUS

[S0]

#### PROPRIETARY NAME AND DOSAGE FORM

NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS (sugar coated tablet)

#### COMPOSITION

Active Ingredients	per tablet	per 2 tablets (maximum daily dose)	% NRV # per tablet
<b>Probiotic blend containing:</b>			
<i>Bifidobacterium lactis</i> BI-04			
<i>Lactobacillus rhamnosus</i> GG ATCC-53103	1,5 billion cfu	3 billion cfu	-
<i>Lactobacillus acidophilus</i> La-14			
<i>Lactobacillus plantarum</i> Lp-115			
Vitamin D3 (Cholecalciferol)	400 IU (10 µg)	800 IU (20 µg)	67

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

Excipients: calcium carbonate, cocoa solids, edible gum, emulsifiers (E322, E476), glazing agent (E901), food colours (E102, E110, E124, E127, E132, E133), flavouring, hydrogenated vegetable fat. Contains sugar (sucrose 558 mg/ tablet).

#### CATEGORY AND CLASS

D.34.9 Complementary Medicines: Health Supplements – Probiotics.

#### PHARMACOLOGICAL ACTION

##### Pharmacodynamic properties

Probiotics are "friendly" microbiota and are taken in order to recolonize areas of the body where they would normally occur. The body is dependent on the endemic microbiota for functions such as metabolism, nutrient absorption, and preventing colonization by pathogenic microbiota.

##### Pharmacokinetic properties

For continued effect, probiotics must be used regularly. *Lactobacilli* pass through the gut and attach to the intestinal mucosa where they can persist for at least one week. *Bifidobacteria* can persist for at least 2 weeks.

#### INDICATIONS

NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS is a probiotic containing supplement that when ingested on a regular basis, should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut. NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS also contains vitamin D3 to help support the development of healthy teeth and bones.

#### CONTRAINDICATIONS

Hypersensitivity to any of the ingredients of NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS (see **COMPOSITION**). NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS is contraindicated to those that suffer from immune-compromised conditions (e.g. AIDS, lymphoma or patients undergoing long-term corticosteroid treatment)

#### WARNINGS AND SPECIAL PRECAUTIONS

Do not use if known hypersensitivity or allergy exists to any of the ingredients. If in doubt, consult your medical practitioner. The ingredients in NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS may interact with antibiotics (see **INTERACTIONS**). Consult a healthcare practitioner before use if you have fever, vomiting, bloody diarrhoea or severe abdominal pain. Stop use and consult a healthcare practitioner if symptoms of digestive upset (such as diarrhoea) occur, worsen and/or persists for longer than 3 days.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS.

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

#### Effects on ability to drive vehicles and use machines

NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS 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.

#### INTERACTIONS

Take NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS a few hours before or after taking other medications (see **DOSAGE AND DIRECTIONS FOR USE**).

NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS should not be taken with antibiotics or antifungal medications, as these medications may reduce the efficacy of the NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS. It is recommended that all oral antibiotics are taken at least two (2) hours before, or after NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS or similar supplements.

#### HUMAN REPRODUCTION

##### Pregnancy

It is not advisable to take NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS while you are pregnant.

##### Women of Childbearing Potential

There are no known restrictions for use of NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS in women of childbearing age.

##### Lactation

It is not advisable to take NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS while you are breastfeeding.

##### Fertility

There are no known effects of NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS on fertility.

#### DOSAGE AND DIRECTIONS FOR USE

##### Dosage

Do not exceed the recommended daily dosage.

*Children 3 years and older:* Give 1 - 2 tablets daily.

##### Directions for use

Given daily in the morning before breakfast.

It is recommended to take Nativa Complex® JUNIOR PROBIOTIC CHOCO BUTTONS at least 2 hrs before or after antibiotic medication.

#### SIDE EFFECTS

If you experience any side effects or sensitivity towards any of the ingredients, discontinue use.

If symptoms persist, or if any adverse reactions occur, consult a medical practitioner.

Side effects may include, but are not limited to:

#### Gastrointestinal disorders

*Frequency unknown:* dyspepsia (including upper abdominal (epigastric) discomfort and nausea), flatulence, belching, bloating and diarrhoea

#### Skin and subcutaneous tissue disorders:

*Frequency unknown:* hypersensitivity reaction (skin rash and itching)

#### Product issues

No product issues are available on NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS.

#### Post-marketing data

No side effects of NATIVA COMPLEX® JUNIOR PROBIOTIC CHOCO BUTTONS have been reported post-marketing.

#### KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

##### Symptoms of Overdosage

See **SIDE EFFECTS**.

Do not exceed the recommended daily dosage.

##### Treatment of Overdosage

If an accidental overdose occurs, consult a medical practitioner.

Treatment is symptomatic and supportive.

#### IDENTIFICATION

Red, green and yellow sugar coated chocolate tablets.

#### PRESENTATION

White high density polyethylene plastic container with polypropylene silver flip-top cap, containing 30 sugar coated chocolate tablets, and a leaflet in a unit carton.

#### STORAGE INSTRUCTIONS

Do not use if seal is broken.

Store at or below 25 °C.

The product may be refrigerated, if needed.

Replace cap firmly after use.

Protect from light and moisture.

Keep in original packaging until required for use.

Do not use after the expiry date printed on the carton and label.

KEEP OUT OF REACH OF CHILDREN.

#### REGISTRATION NUMBER

To be allocated

#### NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Nativa (Pty) Ltd

260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa

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Email: health@nativa.co.za

Website: www.nativa.co.za

#### DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

To be allocated

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To be allocated

#### COMPLEMENTARY MEDICINE

Health Supplement

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.

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