

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE (HEALTH SUPPLEMENT)

SCHEDULING STATUS S0

1. NAME OF THE MEDICINE

NutriPure Adult Probiotics (multiple substances, gummies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:

<i>Bifidobacterium Infantis</i>	1 x 10 ⁹ CFU
<i>Lactobacillus rhamnosus</i>	1 x 10 ⁹ CFU
Nicotinamide (Niacin)	16 mg
Calcium d-pantothenate (Pantothenic acid)	6,0 mg
Pyridoxine hydrochloride (Vitamin B6)	1,4 mg

Contains sugar: Glucose syrup (0,90 g); Sucrose (0,71 g)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gummies

NutriPure Adult Probiotics gummies is grape-shaped, red gummies with a characteristic redberry taste and odour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

When ingested on a regular basis, probiotics should improve or normalize the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut.

4.2. Posology and method of administration

Posology

Adults: Take one (1) to two (2) gummies daily.

Not suitable for children (see section **4.3 Contraindications**).

Method of administration

Take the chewable gummies orally.

Do not take on an empty stomach. It is best to be taken with a meal.

4.3. Contraindications

This product should not be used by patients who have an allergy or are hypersensitive to any of the ingredients.

Not suitable for children (see section **4.2 Posology**).

Insufficient reliable information is available for use during pregnancy and lactation. (see section **4.6. Fertility, pregnancy and lactation**).

4.4. Special warnings and precautions for use

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take NutriPure Adult Probiotics Gummies.

Contains glucose syrup and sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

There is some concern that bifidobacterial and lactobacillus preparations might cause pathogenic colonization in patients who are immunocompromised; however, this is more likely to occur in severely immunocompromised patients. Use with caution in these patients.

Patients with short bowel syndrome might be predisposed to pathogenic infection from Lactobacillus. Use NutriPure Adult Probiotics with caution in patients with this condition.

Do not exceed the stated recommended daily dose without consulting a relevant health care provider.

Consult a relevant health care provider prior to use if you are pregnant or breastfeeding, as safety has not been established (see section **4.6. Fertility, pregnancy and lactation**).

4.5. Interactions with other medicines and other forms of interaction

Interaction with medicines

ANTIBIOTIC MEDICINES: There is some concern that concomitant administration of certain antibiotics might decrease the effectiveness of bifidobacterial. Since bifidobacterial preparations usually contain live and active organisms, simultaneously taking antibiotics might kill a significant number of the organisms. Tell patients to separate administration of antibiotics and NutriPure Adult Probiotics by at least 2 hours.

ALCOHOL: Concomitant use of alcohol and niacin might increase the risk of flushing and hepatotoxicity.

ANTICOAGULANT OR ANTIPLATELET MEDICINES: Niacin may have additive effects when used with anticoagulant or antiplatelet medicines.

ANTIHYPERTENSIVE MEDICINES: Niacin may increase the risk of hypotension when used with antihypertensive medicines.

PHENYTOIN: High doses of vitamin B6 may reduce the levels and clinical effects of phenytoin. Advise people taking phenytoin to avoid high doses of vitamin B6. Folic acid might reduce serum levels of phenytoin in some patients.

PHENOBARBITAL: High doses of vitamin B6 may reduce the levels and clinical effects of phenobarbital. Advise people taking phenobarbital to avoid high doses of vitamin B6.

Interaction with Herbs and Supplements

ANTICOAGULANT/ANTIPLATELET HERBS AND SUPPLEMENTS: Niacin may increase the risk of bleeding in some patients.

Interactions with Foods

HOT DRINKS: Niacin-induced flushing and itching might be increased if niacin is taken with a hot drink.

Interactions with Lab Tests

None known.

4.6. Fertility, pregnancy and lactation

Safety in pregnancy and when breastfeeding has not been established, consult a health care provider prior to use (see section **4.4. Special warnings and precautions for use**).

The effect on fertility is unknown.

4.7. Effects on ability to drive and use machines

There is no known effect on the ability to drive and use machines.

4.8. Undesirable effects

The most common adverse effects include bloating, flatulence, gastrointestinal discomfort, diarrhoea, belching, abdominal pain, flushing and elevated liver enzymes.

Orally, lactobacillus species are generally well tolerated, however, there is concern that lactobacillus may cause infections in some people such as immunocompromised individuals.

If adverse effects do occur, please discontinue use and consult your physician.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**” found online under SAHPRA’s publications:
<https://www.sahpra.org.za/Publications/Index/8>.

4.9. Overdose

There is insufficient reliable information available about the presentation or treatment of overdose.

In overdose, side effects can be precipitated and/or be of increased severity (see **section 4.8. Undesirable effects**).

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

D34.12 Multiple substance formulation

NutriPure Adult Probiotics Gummies contains probiotics, vitamins and minerals that are factors in the maintenance of good health. Probiotics are considered "friendly" bacteria and are taken for the purpose of re-colonizing areas of the body where they normally would occur. The human body relies on the normal flora for several functions including metabolizing foods and certain drugs, absorbing nutrients, and preventing colonization by pathogenic bacteria. Lactobacilli seem to provide nutritional benefits including inducing growth factors and increasing the bioavailability of minerals. Lactobacilli also stabilize the mucosal barrier and decrease intestinal permeability. Bifidobacteria are anaerobic, rod-shaped, Gram-positive bacteria that normally colonize in the human colon, while lactobacillus refers to a group of lactic acid producing, gram-positive rods that are obligate and facultative anaerobes. Bifidobacteria appear to be the most important organisms in the intestine for providing a microbial barrier to infection. When used orally, some species of bifidobacteria, such as *Bifidobacterium infantis*, pass through the gut and bind to the intestinal mucosa, preventing attachment of pathogenic coliform bacteria.

Niacin, pyridoxine and pantothenic acid helps to metabolise carbohydrates, fats and proteins. Pantothenic acid is a precursor of coenzyme A (CoA), which is required in the acetylation reactions in gluconeogenesis; in the release of energy from carbohydrates; in the synthesis and degradation of fatty acids; and in the synthesis of sterols, steroid hormones, porphyrins, acetylcholine, and other compounds. Pantothenic acid also appears to be essential to normal epithelial function.

In the body, vitamin B6 is converted to the coenzyme pyridoxal phosphate for a wide variety of metabolic reactions. These reactions include transamination of amino acids, conversion of tryptophan to niacin, synthesis of gamma-aminobutyric acid (GABA) in the CNS, metabolism of

serotonin, norepinephrine and dopamine, metabolism of polyunsaturated fatty acids and phospholipids, and the synthesis of the heme component of haemoglobin.

5.2. Pharmacokinetic properties

There is no clinical pharmacokinetic data available on NutriPure Adult Probiotics to clarify the pharmacokinetic properties.

Bifidobacteria

Absorption

Bifidobacteria are not commonly absorbed in the gastrointestinal tract. *Bifidobacteria* disappear from the faeces within 2 weeks of discontinuation of *Bifidobacteria*, suggesting that there is no long-term colonization. For continued effect, *Bifidobacteria* must be used regularly.

Lactobacillus

Distribution

When taken orally, *Lactobacilli* pass through the gut and attach to the intestinal mucosa where they can persist for at least one week.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Anthocyanines E-163,
carnauba wax,
citric acid,
glucose syrup,
maltodextrine,
pectin,
redberries aroma (flavouring),
sucrose,
sodium citrate,
water,
vegetable oil.

6.2. Incompatibilities

None known.

6.3. Shelf life

The shelf life for NutriPure Adult Probiotics is two years.

6.4. Special precautions for storage

Store at or below 25 °C, tightly closed in a cool, dry place.
KEEP OUT OF REACH OF CHILDREN.

MDI Healthcare cc
NutriPure Adult Probiotics
Multiple substances (gummies)

6.5. Nature and contents of container

NutriPure Adult Probiotics container is a white, 300 ml, plastic PET bottle with a green, push-down-and-turn closure cap and a silver induction liner containing 60 gummies.

6.6. Special precautions for disposal and other handling

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

MDI Healthcare cc
P.O. Box 35259, Menlopark
Pretoria
0102

Marketed by:

NutriPure Healthcare
P.O. Box 16645,
Vlaeberg,
8018,
Cape Town.

8. REGISTRATION NUMBER(S):

To be allocated.

1. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be allocated.

2. DATE OF REVISION OF THE TEXT

April 2023.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.
