

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE (DISCIPLINE-SPECIFIC – COMBINATION PRODUCTS)

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. Health Supplements should not be used as a substitute for a varied and balanced diet and healthy lifestyle.

SCHEDULING STATUS S0

1. NAME OF THE MEDICINE

NUTRIPURE TEENS CLEAR SKIN (multiple substance, gummies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:

L-Ascorbic Acid (Vitamin C)	40 mg
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<i>Oryza sativa</i> L. (Rice Bran)	30 mg
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[bran, extract standardized to
ceramides 10 %]

<i>Centella asiatica</i> (L.) Urb (Gotu Kola)	10 mg
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[whole part, extract standardized to

asiaticosides 20 %]

Zinc Citrate	5,38 mg
providing Zinc (elemental)	1,5 mg
D-Biotin (Biotin)	50 µg
<i>Lactiplantibacillus plantarum</i> (L. plantarum)	0,5 Billion Cells

Contains sugar: Glucose syrup (1,27 g); Sucrose (1,07 g)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gummies

NUTRIPURE TEENS CLEAR SKIN is a red, bear-shaped gummy, red berries flavour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

NUTRIPURE TEENS CLEAR SKIN is a complementary medicine formulated for teenage skin health. It contains biotic cultures, Centella, rice bran extract, biotin, zinc and vitamin C. Biotin and zinc contribute to the maintenance of normal skin. Vitamin C

supports normal immune function and contributes to the protection of cells from oxidative stress.

4.2. Posology and method of administration

Posology

Ages 13 years and older: Take two gummies daily.

For use by teenagers only under adult supervision (see **4.4. Special warnings and precautions for use**).

Do not give to children under 13 years old (see **4.3. Contraindications**).

Do not exceed daily dosage level without consulting a relevant health care provider (see **4.4. Special warnings and precautions for use**).

Method of administration

Take orally.

4.3. Contraindications

NUTRIPURE TEENS CLEAR SKIN should not be used in patients with hypersensitivity to any of the active substances or to any of the excipients listed in **section 6.1**.

Do not give to children under 13 years old.

4.4. Special warnings and precautions for use

Do not exceed daily dosage level without consulting a relevant health care provider (see section **4.2 Posology and method of administration**).

For use by teenagers only under adult supervision.

Patients should consult a relevant health care provider before using **NUTRIPURE TEENS CLEAR SKIN** if they:

- are pregnant or breastfeeding;
- have liver disease;
- are severely immunocompromised;
- have valvular heart disease;
- are taking sedative medicines or medicines that may affect the liver; or
- are scheduled for surgery.

Rare cases of hepatotoxicity have been reported following oral use of gotu kola.

Discontinue use and consult a relevant health care provider if signs or symptoms suggestive of liver dysfunction occur.

If symptoms worsen, consult a relevant health care provider.

NUTRIPURE TEENS CLEAR SKIN contains approximately 1,27 g glucose syrup and 1,07 g sucrose per gummy. This should be considered in patients with diabetes mellitus or those following a sugar-controlled diet.

Health supplements should not be used as a substitute for a varied and balanced diet and a healthy lifestyle.

4.5. Interactions with other medicines and other forms of interaction

No interaction studies have been performed with **NUTRIPURE TEENS CLEAR SKIN**.

Antibiotics

Antibiotics may reduce the effectiveness of *Lactiplantibacillus plantarum* by reducing the number of viable organisms. **NUTRIPURE TEENS CLEAR SKIN** should be administered at least two hours before or after an antibiotic.

Zinc may reduce the absorption of tetracycline and quinolone antibiotics. Administration should be separated in accordance with the prescribing information of the antibiotic.

Sedative medicines

Gotu kola may theoretically increase the effects of central nervous system depressants and other sedative medicines. Concurrent use should be undertaken with caution.

Hepatotoxic medicines

Gotu kola may theoretically increase the risk of liver injury when used concomitantly with medicines that may affect liver function.

Laboratory tests

Biotin may interfere with laboratory tests that use biotin-streptavidin technology and may result in falsely increased or decreased results. The clinical relevance at the recommended dosage is expected to be low.

Vitamin C may interfere with certain laboratory tests. This interaction is unlikely at the amount contained in **NUTRIPURE TEENS CLEAR SKIN**.

4.6. Fertility, pregnancy and lactation

Consult a relevant health care provider prior to use if you are pregnant or breastfeeding (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

NUTRIPURE TEENS CLEAR SKIN is generally well tolerated when used at the recommended dose.

Hypersensitivity reactions, including urticaria and angioedema, may occur in susceptible individuals.

Gastrointestinal adverse effects, including nausea, abdominal discomfort, diarrhoea, flatulence and altered bowel habits, may occur.

Rare cases of hepatotoxicity have been reported following oral use of gotu kola.

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. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9. Overdose

There is limited information available regarding overdose with **NUTRIPURE TEENS CLEAR SKIN**.

Overdose may increase the likelihood and severity of adverse effects associated with the individual ingredients, particularly gastrointestinal adverse effects.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Complementary Medicine – Discipline specific

D 33.7 Combination products

Vitamin C

Vitamin C is a water-soluble antioxidant and a cofactor for several enzymatic reactions.

It contributes to collagen synthesis, connective tissue formation, wound healing, immune function and the protection of cellular components against oxidative damage.

Rice bran extract

Rice bran contains constituents with antioxidant activity. In vitro, rice bran has demonstrated free-radical scavenging activity.

Gotu kola

Gotu kola contains triterpene constituents, including asiaticosides. Triterpene constituents of gotu kola have demonstrated effects on collagen synthesis, fibroblast proliferation and connective tissue repair.

Zinc

Zinc is an essential trace element and acts as a structural, catalytic or regulatory component of numerous enzymes and proteins.

Zinc contributes to DNA, RNA and protein synthesis, immune function, growth and development and tissue repair.

Biotin

Biotin is a water-soluble vitamin that functions as a cofactor for carboxylase enzymes involved in fatty-acid synthesis, gluconeogenesis and amino-acid metabolism.

Lactiplantibacillus plantarum

Lactiplantibacillus plantarum is a lactic acid-producing bacterium used as a probiotic.

When viable, it may colonise the gastrointestinal tract and contribute to maintenance of the intestinal microbiota.

5.2. Pharmacokinetic properties

Pharmacokinetic studies have not been conducted with **NUTRIPURE TEENS CLEAR SKIN**.

Vitamin C is absorbed from the gastrointestinal tract by a saturable transport mechanism. Oral absorption is higher at lower doses and decreases with increasing doses. Most absorbed vitamin C is excreted in the urine.

Zinc is absorbed from the gastrointestinal tract. Absorption is influenced by dietary factors, particularly phytate content. Most zinc is excreted in the faeces, with a small amount eliminated in the urine.

Biotin is absorbed from the gastrointestinal tract and transported by a sodium-dependent multivitamin transport system. Biotin and its metabolites are primarily excreted in the urine.

Lactiplantibacillus plantarum is not systemically absorbed from the gastrointestinal tract.

Some viable preparations may colonise the large bowel.

Pharmacokinetic data for gotu kola and rice bran extract are limited.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Water

Fruit juice concentrate

Gelling agent (Pectin)

Acid (Citric acid)

Acidity regulator (Sodium citrate)

Flavouring

Colour (Anthocyanins)

Coconut oil

Glazing agent (Carnauba wax)

6.2. Incompatibilities

None known.

6.3. Shelf life

The shelf life for **NUTRIPURE TEENS CLEAR SKIN** is two years.

6.4. Special precautions for storage

Store below 25 °C in a cool, dry place.

Keep bottle tightly closed.

6.5. Nature and contents of container

NUTRIPURE TEENS CLEAR SKIN is supplied in a clear 300 ml PET bottle (60's) with light green CRC cap and silver induction liner.

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, Menlo Park

Pretoria

0102

8. REGISTRATION NUMBER(S):

To be allocated.

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

To be allocated.

10. DATE OF REVISION OF THE TEXT

To be allocated.