

Category D: Complementary Medicine**Health Supplements: D 34.12 Multiple Substance Formulation**

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

SCHEDULING STATUS

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1. NAME OF THE MEDICINE**Prosana Hair & Nail Booster Tablets****Multiple Substance Formulation****2. QUALITATIVE AND QUANTITATIVE COMPOSITION****Each tablet contains:**

Choline bitartrate providing Choline	125 mg 51 mg
Inositol	100 mg
Hydrolysed collagen (bovine)	50 mg
<i>Glycine max</i> (L.) Merr. (Soya protein)	50 mg
Para Aminobenzoic acid	20 mg
Nicotinamide (Vitamin B ₃)	20 mg
Ferrous gluconate providing Iron (elemental)	18 mg 2,0 mg
Zinc gluconate providing Zinc (elemental)	15 mg 1,9 mg
Manganese glycinate providing Manganese (elemental)	15 mg 1,5 mg
Calcium d-Pantothenate (Vitamin B ₅)	6,5 mg
Folic acid	200 µg
D-Biotin (Vitamin H)	225 µg
Copper sulphate providing Copper (elemental)	142 µg 55 µg
Cyanocobalamin (Vitamin B ₁₂)	6 µg

Contains sugar: Sucrose 39,4 mg/tablet.

Contains sweetener: Mannitol 83 mg/tablet.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

White, round, sugar-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prosana Hair & Nail Booster Tablets contains vitamins, minerals and amino acids which contributes to the maintenance of normal hair and nails, and normal hair pigmentation.

4.2 Posology and method of administration

Posology

Adults 18 years and older: Take 1 to 2 tablets once daily.

Do not exceed daily dosage level without consulting a relevant healthcare provider.

Method of administration

Oral use.

Prosana Hair & Nail Booster Tablets should be taken after food with sufficient liquid.

Paediatric population

Prosana Hair & Nail Booster Tablets should not be taken by children under the age of 18 years.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients listed in section 2 or to any of the excipients listed in section 6.1.
- Hypersensitivity to soya (see section 4.4).
- Concomitant use with sulphonamides (see section 4.5)
- Children under the age of 18 years.

4.4 Special warnings and precautions for use

- Advise patients suffering from any medical condition, or who are taking any medicine, or who are pregnant or lactating to consult a healthcare provider before taking **Prosana Hair & Nail Booster Tablets**.
- **Prosana Hair & Nail Booster Tablets** contains soya protein. Individuals who are allergic to soya, should not use **Prosana Hair & Nail Booster Tablets** (see section 4.3).

- Patients should be advised to stop use and consult a relevant healthcare provider if hypersensitivity or allergy occurs.
- Collagen, as in **Prosana Hair & Nail Booster Tablets**, may cause mild gastrointestinal disturbances.
- Exercise caution when recommended to individuals who may have insulin resistance, high blood glucose levels or have diabetes.
- Inform patients that sufficient protein is provided in normal well-balanced daily meals.
- **Prosana Hair & Nail Booster Tablets** contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take **Prosana Hair & Nail Booster Tablets**.

4.5 Interaction with other medicines and other forms of interaction

- Concomitant use of soya protein, as in **Prosana Hair & Nail Booster Tablets**, with antidiabetic medicines (e.g. metformin) may interfere with blood glucose control by reducing the glucose level. Caution is advised during concomitant use.
- Para aminobenzoic acid (PABA), as in **Prosana Hair & Nail Booster Tablets**, inhibits the antimicrobial activity of sulfonamide antibiotics by competitively inhibiting folic acid synthesis from PABA. **Prosana Hair & Nail Booster Tablets** should not be taken together with sulfonamide antibiotics (see section 4.3).
- Iron and manganese (as in **Prosana Hair & Nail Booster Tablets**) may decrease the absorption of tetracycline (e.g. minocycline) and quinolone (e.g. ciprofloxacin) antibiotics. Doses should be separated by at least 2 hours prior to, or 4 to 6 hours after taking **Prosana Hair & Nail Booster Tablets**.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

No fertility data is available.

4.7 Effects on ability to drive and use machines

Prosana Hair & Nail Booster Tablets can cause side effects, such as dizziness or drowsiness. Caution is advised when driving a vehicle or operating machinery until the effects of **Prosana Hair & Nail Booster Tablets** are known.

4.8 Undesirable effects

a) *Summary of the safety profile*

Prosana Hair & Nail Booster Tablets is generally well-tolerated.

b) Tabulated list of adverse reactions

SYSTEM ORGAN CLASS	FREQUENCY	ADVERSE REACTIONS
Immune system disorders:	<i>Less frequent</i>	allergic reactions
Nervous system disorders:	<i>Less frequent</i>	dizziness, drowsiness, headache
Gastrointestinal disorders:	<i>Less frequent</i>	mild gastrointestinal disturbances, diarrhoea, gas, nausea, constipation, bloating, abdominal pain, gastrointestinal irritation, vomiting, abdominal cramps, metallic taste
Skin and subcutaneous tissue disorders:	<i>Less frequent</i>	itching, rash

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 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

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category D: Complementary Medicine

Health Supplements: D 34.12 Multiple substance formulation

ATC code: A11A Multivitamin, combinations

Choline is a factor in the maintenance of good health and is required for the structure of cell membranes.

Hydrolysed collagen is a source of essential amino acids and is a factor in the maintenance of good health and involved in protein synthesis.

Iron is a trace mineral that helps to form red blood cells and helps in their proper function.

Zinc is a trace element that contributes to the maintenance of normal hair and nails, and helps to maintain healthy skin.

D-Biotin contributes to the maintenance of normal hair and skin. D-Biotin has been shown to improve brittle nails by inducing epidermal differentiation.

Copper contributes to normal hair and skin pigmentation, and helps to produce and repair connective tissue.

Folic acid helps to metabolise proteins and helps to form red blood cells.

Manganese, Vitamin B₃, Vitamin B₅ and Vitamin B₁₂ help the body to metabolise carbohydrates, fats and protein.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brewer's yeast

Magnesium stearate

Mannitol

Nutrafinish translucent (containing glyceryl monostearate, hydroxypropyl methyl cellulose, medium chain triglycerides (vegetable origin), polyethylene glycol/macrogol, sucrose and talc)

Nutrafinish white (containing hydroxypropyl methyl cellulose, medium chain triglycerides (vegetable origin), polyethylene glycol/macrogol, polyvinyl alcohol, sucrose, talc and titanium dioxide)

Povidone K30.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

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

Keep in the original container until required for use.

6.5 Nature and contents of container

Blister strips containing 20 tablets, packed into an outer carton.

Pack sizes: 60 or 180 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand 1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER

To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Not applicable

10. DATE OF REVISION OF THE TEXT

April 2024

PI COM10007

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