

PROFESSIONAL INFORMATION
Prosana Hair & Nail Booster Intensive Capsules

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 Intensive Capsules

Multiple Substance Formulation

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Choline bitartrate	125 mg
providing Choline	51 mg
<i>Glycine max</i> (L.) Merr. (Soya protein)	50 mg
Ferrous gluconate	36 mg
providing Iron (elemental)	4 mg
Zinc gluconate	30 mg
providing Zinc (elemental)	3,8 mg
Manganese glycinate providing	23 mg
Manganese (elemental) and	2,3 mg
Glycine	6,2 mg
Para aminobenzoic acid	20 mg
Nicotinamide (Vitamin B ₃)	20 mg
L-Cystine	10 mg
L-Cysteine	10 mg
Taurine	10 mg
Calcium d-Pantothenate	9,2 mg
providing Pantothenic acid (Vitamin B ₅)	8 mg
Copper Glycinate	1,6 mg
providing Copper (elemental)	155 µg
D-Biotin (Vitamin H)	500 µg
Folic acid	400 µg
Cyanocobalamin (Vitamin B ₁₂)	10 µg

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Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Off-white to cream speckled powder, in a white capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prosana Hair & Nail Booster Intensive Capsules contains vitamins, minerals and amino acids which contribute 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 capsule once daily.

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

Method of administration

Oral use.

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

Paediatric population

Prosana Hair & Nail Booster Intensive Capsules 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 sulphonamide antibiotics (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

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who are pregnant or lactating to consult a healthcare provider before taking **Prosana Hair & Nail Booster Intensive Capsules**.

- **Prosana Hair & Nail Booster Intensive Capsules** contains soy protein. Individuals who are allergic to soya, should not use **Prosana Hair & Nail Booster Intensive Capsules** (see section 4.3).
- Patients should be advised to stop use and consult a relevant healthcare provider if hypersensitivity or allergy occurs.
- Inform patients that sufficient protein is provided in normal well-balanced daily meals.

4.5 Interaction with other medicines and other forms of interaction

- Concomitant use of soya protein, as in **Prosana Hair & Nail Booster Intensive Capsules**, 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 Intensive Capsules**, inhibits the antimicrobial activity of sulfonamide antibiotics by competitively inhibiting folic acid synthesis from PABA. **Prosana Hair & Nail Booster Intensive Capsules** should not be taken together with sulfonamide antibiotics (see section 4.3).
- Iron and manganese (as in **Prosana Hair & Nail Booster Intensive Capsules**) 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 Intensive Capsules**.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Prosana Hair & Nail Booster Intensive Capsules 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 Intensive Capsules** are known.

4.8 Undesirable effects

a) Summary of the safety profile

Prosana Hair & Nail Booster Intensive Capsules is generally well-tolerated.

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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>	bloating, constipation, diarrhoea, nausea, vomiting, abdominal pain, abdominal cramps, metallic taste, gastrointestinal disturbances, dyspepsia
Skin and subcutaneous tissue disorders:	<i>Less frequent</i>	rash, itching

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 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

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ATC code: A11A Multivitamin, combinations

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

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.

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

L-cystine and L-cysteine are sources of non-essential amino acids involved in protein synthesis. Proteins are constituents of living cells essential for growth and repair of tissues. Taurine is an amino acid and antioxidant. It is important in several metabolic processes in the body.

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

Capsule (containing hypromellose)

Dicalcium phosphate dihydrate

Magnesium stearate

Silicon dioxide

Talc.

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 10 capsules, packed into an outer carton.

Pack size: 30 or 90 capsules.

Not all pack sizes shall be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

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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

June 2024

adcock ingram 

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