

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

Xtreme C Boost, tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Ingredients	Per tablet
Ascorbic Acid (Vitamin C)	1000,00 mg
Thiamine HCL (Vitamin B ₁)	1,18 mg
Riboflavin (Vitamin B ₂)	1,28 mg
Pantothenic acid (Vitamin B ₅)	4,95 mg
Nicotinamide (Vitamin B ₃)	15,79 mg
Pyridoxine HCL (Vitamin B ₆)	1,69 mg
Cyanocobalamin (Vitamin B ₁₂)	2,40 mcg
Folic acid	0,40 mg
Cholecalciferol (Vitamin D ₃)	12,50 mcg 500 IU
Magnesium lactate providing Magnesium (elemental)	7,50 mg 0,90 mg
Zinc gluconate providing Zinc (elemental)	11,0 mg 1,54 mg

Sugar free.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oval, smooth bright orange coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Xtreme C Boost tablets is a Vitamin C and multivitamin supplement with antioxidant benefits that are important for healthy bones, teeth, gums, skin, joints and tendons. Assists with healthy immune system, healing process and coping with stress.

4.2 Posology and method of administration

Adults and children 14 years and older: Take 1 tablet daily, after main meal, with a glass of water.

The recommended dose should not be exceeded.

Method of administration

For oral use.

4.3 Contraindications

Contraindicated in patients with an allergic hypersensitivity to any of the ingredients.

Unless otherwise prescribed, do not exceed the stated dose. Vitamin supplements should not replace a balanced diet.

4.4 Special warnings and precautions for use

When prescribing Xtreme C Boost tablets, as with all multi-vitamin preparations, allowance should be made for vitamins obtained from other sources.

4.5 Interaction with other medicines and other forms of interaction

None known at recommended dosage.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on the ability to drive and use machines

No known effect on an individual's ability to drive or operate machinery.

4.8 Undesirable effects

Allergic reactions have been reported with vitamin use and include:

- Rash
- Pruritis

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It follows 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

Treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category D Complementary Medicine: Health Supplement: D34.12 Multiple Substance Formulation

5.2 Pharmacokinetic properties

Xtreme C Boost tablets consists out of a combination of vitamin C and other vitamins. Pharmacokinetic studies on Xtreme C Boost tablets as a combination product have not been conducted.

5.3 Preclinical safety data

No data available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Other Ingredients: Magnesium stearate, aerosil, polyvinylpyrrolidone, polyethylene glycol and microcrystalline cellulose.

6.2 Incompatibilities

Unknown

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Keep in a dry, cool place.

Store in the original container to protect from light and moisture.

6.5 Nature and contents of container

30 tablets in container with orange lid.

6.6 Special precautions for disposal

No special requirements. Any unused product should be disposed of in accordance with local requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Astral Pharma (Pty) Ltd

49 Riboville Road

Randjiesfontein

Midrand

1683

8. REGISTRATION NUMBER

To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be determined

10. DATE OF REVISION OF TEXT

October 2024