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, tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:
Ascorbic Acid 500 mg
Citrus Bioflavonoids 10 mg
Sugar free.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Round, off-white tablets with a breakline and brown speckles.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Xtreme C tablets is a vitamin C and antioxidant supplement.

4.2 Posology and method of administration
Posology
Adults:
Take 1-2 tablets a day, after food with a full glass of water.
Maximum daily dosage is 1000 mg.
Elderly:
As for other adults. As the dietary intake of vitamin C may be less in the elderly, they have greater risk of presenting with vitamin C deficiency.
Method of administration
For oral administration.

4.3 Contraindications
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- It is a supplement and not intended for a specific vitamin deficiency.

4.4 Special warnings and precautions for use
Keep out of reach of children.
Unless otherwise prescribed, do not exceed the stated recommended daily dosage. Vitamin supplements should not replace a balanced diet.

4.5 Interaction with other medicines and other forms of interaction
None known at the recommended dosage.

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
Ascorbic acid has 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 may include
- rash
- pruritus.

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. 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
Symptoms
Large doses of ascorbic acid may cause diarrhoea and the formation of renal oxalate calculi.
Management
Treatment is supportive and symptomatic.
Should accidental overdose occur, discontinue use and consult a pharmacist or doctor.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category D Complementary Medicine – Health Supplement: 33.7 Combination Product.
This medicine is not intended to diagnose, treat, cure or prevent any disease.

5.2 Pharmacokinetic properties
Absorption
Ascorbic acid is well absorbed from the gastrointestinal tract.
Distribution
Ascorbic acid is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1.5 g. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma.
Elimination
Ascorbic acid additional to the body's needs, generally amounts above 200 mg daily, is rapidly eliminated; unmetabolized ascorbic acid and its inactive metabolic products are chiefly excreted in the urine. The amount of ascorbic acid excreted unchanged in the urine is dose-dependent and may be accompanied by mild diuresis.

5.3 Preclinical safety data
Not known.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Microcrystalline cellulose PH101
Silicon Dioxide
Stearic Acid (Sterlipress)

6.2 Incompatibilities
None known

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store in a cool, dry place at or below 25 °C.
Store in the original package to protect from light and moisture.
Keep the container firmly closed.

6.5 Nature and contents of container
Plastic containers (securitainers) fitted with orange plastic caps.
Pack sizes: 100, 1000
Not all pack sizes may be marketed.

6.6 Special precautions for disposa
No special requirements for disposal. Any unused product should be disposed of in accordance with local requirements

7. THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Astral Pharma (Pty) Ltd
49 Riboville Road
Randjiesfontein
Midrand
1683

8. REGISTRATION NUMBER(S)
To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
January 2018

10. DATE OF REVISION OF TEXT
September 2024