

Stellar Activ-FOLATE® Film-coated Tablets

PROFESSIONAL INFORMATION

Complementary Medicine – Health Supplement

SCHEDULING STATUS

To be assigned

1. NAME OF THE MEDICINE

Stellar Activ-FOLATE® Film-coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Peach Tablet contains:

Folate derived from (6S)-5-Methyltetrahydrofolate	500	µg
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Sucrose, Lactose, Gluten and Tartrazine Free.

3. PHARMACEUTICAL FORM

Film-coated Tablets.
Peach Round Film-coated Tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Stellar Activ-FOLATE® is a health supplement for adults intended as nutritional support where deficiency is at highest risk, for example, prior to conception, during pregnancy or where the medication you are taking interferes with folate metabolism or absorption.

4.2 Posology and method of administration

For oral use.

Take one Peach Stellar Activ-FOLATE® tablet daily with a meal.

Take 2 hours before or after taking other medications or natural health products.

4.3 Contraindications

Do not use if you have a hypersensitivity to any of the ingredients, including excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Stellar Active-FOLATE® should not be given to children below the age of 14 years (due to the high Folate content) unless under the direct supervision of a qualified healthcare professional.

4.5 Interactions with other medicines

None.

4.6 Fertility, Pregnancy and Breastfeeding

Always check with your doctor before taking any medicines if you are pregnant, planning to have a baby or breastfeeding.

The ingredients in Stellar Activ-FOLATE® are safe to use during fertility, pregnancy, and breastfeeding.

4.7 Effects on ability to drive and use of machines

None.

4.8 Undesirable effects

Organ System	Less Frequent
Gastrointestinal discomfort	Nausea, diarrhoea, constipation, indigestion, bloating and flatulence

Reporting of suspected adverse reactions:

If you experience any adverse reactions not mentioned in this leaflet, report it to AnaStellar Brands (Pty) Ltd via pharmacist@anastellar.co.za, (011) 792 4601 or <https://anastellar.co.za>

4.9 Overdose

Treatment of overdose should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Folate: Folates are involved in a number of single carbon transfer reactions, especially in the synthesis of purines and pyrimidines (and hence the synthesis of deoxyribonucleic acid (DNA)), glycine and methionine. They are also involved in some amino acid conversions and the formation and utilisation of formate. Deficiency leads to impaired cell division (effects most noticeable in rapidly regenerating tissues).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:

Calcium Carbonate
Magnesium Stearate
Microcrystalline Cellulose
Silicon Dioxide

Tablet Coating:

Castor Oil
Flexicoat Peach
Shellac

6.2 Incompatibilities

None.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.
Protect from light and moisture.
Keep the blister strips in the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Stellar Activ-FOLATE® is available in a pack of 30 and 120 Peach Round Film-coated Tablets.

30's Pack:

10 x Peach Round Film-coated Tablets contained in 3 x PVC/PVDC/Aluminium blister strips.

120's Pack:

10 x Peach Round Film-coated Tablets contained in 12 x PVC/PVDC/Aluminium blister strips.

Packed product:

30's Pack:

3 x Blister strips enclosed within a cardboard carton.
Pack size of 30 x Peach Film-coated Tablets.

120's Pack:

12 x Blister strips enclosed within a cardboard carton.
Pack size of 120 x Peach Film-coated Tablets.

6.6 Special precautions for disposal

No special requirements.

7. Holder of Certificate of Registration

AnaStellar Brands (Pty) Ltd.
PO Box 639, Fontainebleau
2032
South Africa
+27 (0)11 792 4601

8. Registration number

TBC

9. Date of first authorisation

TBC

10. Date of revision of the text

January 2024

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