PACKAGE INSERT

SCHEDULING STATUS
To be assigned

PROPRIETARY NAME AND DOSAGE FORM
Activ-FOLATE Tablets

COMPOSITION

Each Peach Tablet contains:	
Folate as (6S)-5-Methyltetrahydrofolate	500 µg

Excipients: calcium carbonate, Flexicoat® peach, magnesium stearate (vegetable), microcrystalline cellulose, shellac, silicon dioxide

PHARMACOLOGICAL CLASSIFICATION
D: 22 (Vitamins): Health Supplement

PHARMACOLOGICAL ACTION
Folic Acid: 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).

INDICATIONS
For 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.

CONTRAINDICATIONS
Hypersensitivity to any of the ingredients, including excipients.

WARNINGS AND SPECIAL PRECAUTIONS
Take 2 hours before or after taking other medications.

INTERACTIONS
Folic acid may reduce the absorption of zinc.

PREGNANCY AND LACTATION
Activ-FOLATE is safe for use during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE
For oral use.
Morning: Take one Peach Tablet daily, or as recommended by your Healthcare Professional.
Take 2 hours before or after taking other medications.

SIDE EFFECTS
May cause mild gastrointestinal disturbances.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
If an overdose is suspected, the medicine should be stopped immediately.

IDENTIFICATION
Peach Round Film-coated Tablet.

PRESENTATION
A cardboard carton containing blister strips of 30 or 120 Peach Tablets.

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

REGISTRATION NUMBER
To be assigned

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
AnaStellar Brands (Pty) Ltd
Boskruin Business Park,
Unit 15, North Wing, Ground Floor,
Bosbok Road, Randpark Ridge, 2169,
Gauteng, Republic of South Africa
+27 (0)11 792 4601

DATE OF PUBLICATION OF THE PACKAGE INSERT
March 2017

This medicine has not been evaluated by the Medicines Control Council.
This medicine is not intended to diagnose, treat, cure or prevent any disease.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
To be assigned

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
Activ-FOLATE 500 µg Tablets

Read all of this leaflet carefully before you start taking Activ-FOLATE

Activ-FOLATE is available without a doctor's prescription, for you to treat a mild condition. Nevertheless you still need to use Activ-FOLATE carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share Activ-FOLATE with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT Activ-FOLATE CONTAINS

Each Peach Tablet contains:	
Folate as (6S)-5-Methyltetrahydrofolate	500 µg

The other ingredients are calcium carbonate, Flexicoat® peach, magnesium stearate (vegetable), microcrystalline cellulose, shellac, silicon dioxide

WHAT Activ-FOLATE IS USED FOR
For 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.

BEFORE YOU TAKE Activ-FOLATE
Do not take Activ-FOLATE if:
- Hypersensitive (allergic) to any of the ingredients of Activ-FOLATE.

Take special care with Activ-FOLATE:
Take Activ-FOLATE 2 hours before or after taking any medication.

Taking Activ-FOLATE with food and drink:
Activ-FOLATE should be taken with food.

Pregnancy and breastfeeding:
Activ-FOLATE should be safe to use during pregnancy and breastfeeding, but always tell your doctor that you are using the product.

Taking other medicines with Activ-FOLATE:
Always tell your healthcare professional if you are taking any other medicine.
This includes complementary or traditional medicines.
Always check with your Doctor or Pharmacist before taking any medicines if you are pregnant or breastfeeding.
Folic acid may reduce the absorption of zinc.

HOW TO TAKE Activ-FOLATE
Do not share medicines with any other person.
You should check with your doctor or pharmacist if you are unsure on how to use Activ-FOLATE.

The usual dose is one Peach Tablet daily, or as recommended by your Healthcare Professional.
Take 2 hours before or after taking other medications.

If you take more Activ-FOLATE than you should:
In the event of an overdosage, consult your doctor or pharmacist.
If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of Activ-FOLATE:
Do not take a double dose to make up for a forgotten individual dose.

POSSIBLE SIDE EFFECTS
Activ-FOLATE can have side effects.
Not all side effects reported for Activ-FOLATE are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.
You may (in exceptional circumstances) experience nausea, diarrhoea, constipation, indigestion, bloating and flatulence while taking Activ-FOLATE.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF Activ-FOLATE
Store all medicines out of reach of children.
Store at or below 25 °C.
Protect from light and moisture.
Keep the blister strips in the outer carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF Activ-FOLATE
A cardboard carton containing blister strips of 30 or 120 Peach Tablets.

IDENTIFICATION OF Activ-FOLATE
Peach Round Film-coated Tablet.

REGISTRATION NUMBER
To be assigned

NAME AND ADDRESS OF REGISTRATION HOLDER
AnaStellar Brands (Pty) Ltd
Boskruin Business Park, Unit 15, North Wing, Ground Floor,
Bosbok Road, Randpark Ridge, 2169, Gauteng, Republic of South Africa
+27 (0)11 792 4601

DATE OF PUBLICATION
March 2017

This medicine has not been evaluated by the Medicines Control Council.
This medicine is not intended to diagnose, treat, cure or prevent any disease.

VOUBILJET

SKEDULERINGSTATUS
Moet toegewys word

EIENDOMSNAAM EN DOSERINGSVORM
Activ-FOLATE Tablette

SAMESTELLING

Elke Perskekleur Tablet bevat:	
Folaat as (6S)-5-Metieltetrahidrofolaat	500 µg

Bindmiddels: kalsiumkarbonaat, Flexicoat® perske, magnesiumstearaat (plant), mikrokristallyne sellulose, skellak, silikondioksied

FARMAKOLOGIESE KLASSIFIKASIE
D: 22 (Vitamiene): Gesondheidsaanvulling

FARMAKOLOGIESE WERKING
Folaat: Folaat is by 'n aantal enkelkoolstof-oordrareaksies betrokke, veral in die sintese van puriene en pirimidiene (en gevolglik die sintese van deoksiribonukleïensuur (DNA)), glisien en metionien. Hulle is ook by sommige aminosuuromsettings en die vorming en benutting van formiaat betrokke. 'n Tekort lei tot belemmerde selverdeling (die uitwerkings is mees merkbaar by weefsel wat vinnig regenereer).

INDIKASIES
Vir voedingsaanvulling waar 'n tekort die hoogste risiko skep, byvoorbeeld voor swangerskap, tydens swangerskap of waar die medikasie wat jy neem met folaatmetabolisme of folaatopname inmeng.

KONTRA-INDIKASIES
Hipersensitiwiteit vir enige van die bestanddele, insluitend bindmiddels.

WAARSKUWINGS EN SPESIALE VOORSORG
Neem 2 uur voor of na ander medikasies.

INTERAKSIES
Foliensuur mag die opname van sink verminder.

SWANGERSKAP EN LAKTASIE
Activ-FOLATE is veilig vir gebruik tydens swangerskap en laktasie.

DOSERING EN GEBRUIKSAANWYSINGS
Vir mondelikse gebruik.
Soggens: Neem een Perske Tablet daagliks, of soos deur jou gesondheidskundige aanbeveel.
Neem 2 uur voor of na ander medikasies.

NEWE-EFFEKTE
Mag ligte gastroïntestinale versteurings veroorsaak.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE OOR DIE BEHANDELING DAARVAN
As 'n oordosis vermoed word, moet die middel dadelik gestaak word.

IDENTIFIKASIE
Perskekleur Ronde Filmbedekte Tablet.

AANBIEDING
'n Kartonhouer wat stulpverpakkingstroke met 30 of 120 Perske Tablette bevat.

BERGINGSAANWYSINGS
Bewaar teen 25 °C of benede.
Beskerm teen lig en vog.
Hou die stulpverpakkingstroke in die buitenste karton.
HOU BUITE DIE BEREIK VAN KINDERS

REGISTRASIENOMMER
Moet toegeken word

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
AnaStellar Brands (Edms) Bpk
Boskruin Business Park,
Eenheid 15, Noordelike Vleuel, Grondverdieping,
Bosbokweg, Randpark Ridge, 2169,
Gauteng, Republiek van Suid-Afrika
+27 (0)11 792 4601

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET
Maart 2017

Hierdie medisyne is nie deur die Medisynebeheerraad geëvalueer nie.
Hierdie medisyne het nie ten doel om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

PASIËNT-INLIGTINGSPAMFLET

SKEDULERINGSTATUS
Moet toegewys word

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM
Activ-FOLATE 500 µg Tablette

Lees hierdie hele pamflet sorgvuldig voordat jy Activ-FOLATE begin neem

Activ-FOLATE is verkrygbaar sonder 'n doktersvoorskrif, sodat jy 'n ligte toestand kan behandel. Nogtans moet jy Activ-FOLATE steeds versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie pamflet. Dit mag nodig wees om hom weer te lees.
- Moenie Activ-FOLATE met 'n ander persoon deel nie.
- Vra jou apteker as jy meer inligting of advies nodig het.
- Raadpleeg 'n dokter as jou simptome erger word of nie verbeter nie.

WAT Activ-FOLATE BEVAT

Elke Perskekleur Tablet bevat:	
Folaat as (6S)-5-Metieltetrahidrofolaat	500 µg

Die ander bestanddele is kalsiumkarbonaat, Flexicoat® perske, magnesiumstearaat (plant), mikrokristallyne sellulose, skellak, silikondioksied

WAARVOOR Activ-FOLATE GEBRUIK WORD
Vir voedingsaanvulling waar 'n tekort die hoogste risiko skep, byvoorbeeld voor swangerskap, tydens swangerskap of waar die medikasie wat jy neem met folaatmetabolisme of folaatopname inmeng.

VOORDAT JY Activ-FOLATE NEEM
Moet nie Activ-FOLATE neem indien:

- Jy hipersensitief (allergies) vir enige van die bestanddele van Activ-FOLATE is.

Wees bedagsaam wanneer jy Activ-FOLATE neem:
Neem Activ-FOLATE 2 uur voor of na ander medikasie.

Activ-FOLATE saam met kos en dranke:
Activ-FOLATE moet saam met kos geneem word.

Swangerskap en borsvoeding:
Activ-FOLATE behoort veilig te wees vir gebruik tydens swangerskap en borsvoeding maar sê altyd vir jou dokter dat jy die produk gebruik.

Ander medisyne saam met Activ-FOLATE:
Sê altyd vir jou gesondheidskundige as jy enige ander medisyne neem.
Dit sluit gesondheidsaanvullings of tradisionele medisyne in.
As jy swanger is of borsvoed, raadpleeg altyd eers jou dokter of apteker voordat jy enige medisyne neem.
Foliensuur mag die opname van sink verminder.

HOE OM Activ-FOLATE TE NEEM
Moenie medisyne met iemand anders deel nie.
As jy onseker is oor hoe om Activ-FOLATE te gebruik, bespreek dit gerus met jou dokter of apteker.

Die gewone dosis is een Perske Tablet daagliks, of soos deur jou gesondheidskundige aanbeveel.
Neem 2 uur voor of na ander medikasies.

As jy meer Activ-FOLATE neem as wat jy behoort:
In die geval van 'n oordosis, kontak jou dokter of apteker.
As nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As jy 'n Activ-FOLATE dosis oorgeslaan het:
Moenie 'n dubbeldosis neem om vir die vergete individuele dosis op te maak nie.

MOONTLIKE NEWE-EFFEKTE
Activ-FOLATE kan newe-effekte hê.
Nie alle newe-effekte wat vir Activ-FOLATE vermeld is, is in hierdie pamflet ingesluit nie.
As jou algemene gesondheid sou versleg of as jy enige ongewenste uitwerkings ondervind terwyl jy hierdie middel neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidskundige vir professionele advies.
Jy mag (onder buitengewone omstandighede) naarheid, diarree, hardlywigheid, slegte spysvertering, opgeblaasde maag en winderigheid ervaar terwyl jy Activ-FOLATE neem.
As jy enige newe-effekte ondervind wat nie in hierdie pamflet genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

BEWARING EN WEGGOOI VAN Activ-FOLATE
Hou alle medisyne buite kinders se bereik.
Bewaar teen 25 °C of benede.
Beskerm teen lig en vog.
Hou die stulpverpakkingstroke in die buitenste karton.
Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

AANBIEDING VAN Activ-FOLATE
'n Kartonhouer wat stulpverpakkingstroke met 30 of 120 Perske Tablette bevat.

IDENTIFIKASIE VAN Activ-FOLATE
Perskekleur Ronde Filmbedekte Tablet.

REGISTRASIENOMMER
Moet toegeken word

NAAM EN ADRES VAN DIE REGISTRASIEHOUER
AnaStellar Brands (Edms) Bpk,
Boskruin Business Park, Eenheid 15, Noordelike Vleuel, Grondverdieping,
Bosbokweg, Randpark Ridge, 2169, Gauteng, Republiek van Suid-Afrika
+27 (0)11 792 4601

DATUM VAN PUBLIKASIE
Maart 2017

Hierdie medisyne is nie deur die Medisynebeheerraad geëvalueer nie. Hierdie medisyne het nie ten doel om enige siekte te diagnoseer, behandel, genees of te voorkom nie.