

## PROFESSIONAL INFORMATION

### HEALTH SUPPLEMENT: VITAMINS

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

SCHEDULING STATUS: S0

### 1. NAME OF THE MEDICINE

**BIOGEN FOLATE FOR HER (VEGETABLE CAPSULES)**

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

|                                                   |           | *%NRV |
|---------------------------------------------------|-----------|-------|
| Magnafolate™ (L-5-Methyltetrahydrofolate Calcium) | 500,00 µg | 125 % |

\*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010)  
 Sugar free.

For full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

VEGETABLE CAPSULES.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

BIOGEN FOLATE FOR HER supports maternal tissue growth during pregnancy and helps reduce the risk of neural tube defects when taken daily before and during early pregnancy. It also promotes protein metabolism, aids in the formation of red blood cells, and contributes to overall health maintenance.

#### 4.2 Posology and method of administration

##### Posology

##### Adults and children 14 years and older:

Take 1 (one) vegetable capsule daily with meals, or as recommended by your healthcare provider.

Swallow the vegetable capsule whole.

Do not exceed the recommended dose.

##### Method of administration

For oral use. To be taken with or after food.

#### 4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.

#### 4.4 Special warnings and precautions for use

- Patients with any medical conditions or who are taking any other medications should be advised to consult with their relevant healthcare provider prior to using BIOGEN FOLATE FOR HER.
- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Not suitable for children below the age of 14 years unless under the direct supervision of a healthcare provider.

#### 4.5 Interactions with other medicines and other forms of interactions

- No interaction studies have been conducted.

#### 4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established.

#### 4.7 Effects on ability to drive and use machines

BIOGEN FOLATE FOR HER is not likely to cause drowsiness. Patients should take caution before performing activities requiring their attention, until they are reasonably certain that BIOGEN FOLATE FOR HER does not adversely affect their performance.

#### 4.8 Undesirable effects

BIOGEN FOLATE FOR HER is generally well tolerated but may cause gastrointestinal discomfort in some patients.

**Gastrointestinal disorders:** *Frequency unknown:* nausea, vomiting, abdominal pain, stomach upset, diarrhoea, and constipation.

#### 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 "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

#### 4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Class and category:** Category D 34.11 Vitamins.

BIOGEN FOLATE FOR HER supports maternal tissue growth during pregnancy and helps reduce the risk of neural tube defects when taken daily before and during early pregnancy. It also promotes protein metabolism, aids in the formation of red blood cells, and contributes to overall health maintenance.

### 5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on BIOGEN FOLATE FOR HER.

The vitamins and minerals in BIOGEN FOLATE FOR HER are well absorbed from the gastrointestinal tract and are widely distributed to all tissues in the body.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Corn Starch, Magnesium stearate, and Silicon dioxide

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

24 months.

### 6.4 Special precautions for storage

Store at or below 25 °C.

Store in a dry place away from direct sunlight and moisture.

Store in the original packaging until required for use.

### 6.5 Nature and contents of the container

The white vegetable capsules are packed in a white 175 ml PET container, with a Biogen Embossed and ribbed screwcap lid.

Pack size: 30 vegetable capsules.

### 6.6 Special precautions for disposal

No special requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen.

23 Stag Road,

Glen Austin,

South Africa.

Tel: 0860 347 243.

Email: [info@biogen.co.za](mailto:info@biogen.co.za)

Website: [www.biogen.co.za](http://www.biogen.co.za)

## 8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

|                                                                                                                                                                                                                       |                                                                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>JOB:</b> : BPS_Biogen Folate_30's                                                                                                                                                                                  | <b>SIZE:</b> 200mm x 240mm                                                                                                                                                                                                                 |
| <b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/> |                                                                                                                                                                                                                                            |
| <b>COLOURS:</b><br><br>K                                                                                                                                                                                              | <b>FINISHING:</b><br><input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss<br><input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing |
| <b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.                                               |                                                                                                                                                                                                                                            |