

# STRESS RELIEF

## PROFESSIONAL INFORMATION

### COMPLEMENTARY MEDICINE: WESTERN HERBAL MEDICINE.

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 STRESS RELIEF FILM COATED TABLETS

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:	
<i>Valeriana officinalis</i> L. (Valerian) [dry root, 4:1 extract providing 400,00 mg of dried herb equivalent]	100,00 mg
<i>Passiflora incarnata</i> L. (Passiflora) [dry aerial parts, 6:1 extract providing 270,00 mg dried herb equivalent]	45,00 mg

Sugar free.

For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Tablets.  
Pale pink, biconvex, film coated tablet.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

BIOGEN STRESS RELIEF is a mild tranquilliser indicated for nervous tension, nervous irritability, nervousness, restlessness and mild anxiety.

#### 4.2 Posology and method of administration

**Adults and children over 12 years of age:**

*Initial dose:* Take 2 tablets with water three times a day.

*After improvement and in less severe cases:* Take 1 tablet with water three times a day.

Do not exceed the recommended dosage.

#### 4.3 Contraindications

- Hypersensitivity to valerian, passion flower or to any of the excipients listed in section 6.1.
- Children under the age of 12 years.

#### 4.4 Special warnings and precautions for use

- Do not use with alcohol.
- Patients should be advised to discontinue BIOGEN STRESS RELIEF at least 2 weeks before elective surgical procedure. Passion flower has central nervous system (CNS) depressant effects and might cause additive CNS depression when combined with anaesthesia and other medications during and after surgical procedures.
- Should the condition not improve within 3 weeks, or if the symptoms persist or worsen, consult your healthcare practitioner.

#### 4.5 Interaction with other medicines and other forms of interaction

Alcohol, barbiturates and benzodiazepines may potentiate the sedative effect.

#### 4.6 Fertility, pregnancy and lactation

Not recommended. Safety and efficacy in pregnancy and lactation have not been established.

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

BIOGEN STRESS RELIEF may cause drowsiness. Patients should take caution when driving a vehicle or operating machinery requiring their attention within 2 hours of consumption, until they are reasonably certain Biogen Stress Relief does not adversely affect their performance.

#### 4.8 Undesirable effects

*Valerian officinalis:*

##### Psychiatric disorders:

*Less frequent:* Restlessness, excitability, uneasiness, agitation, vivid dreams.

##### Nervous system disorders:

*Less frequent:* Dizziness, headache, fatigue, tremor.

##### Cardiac disorders:

*Less frequent:* Tachycardia.

##### Vascular disorders:

*Less frequent:* Hypotension, chest tightness.

##### Gastrointestinal disorders:

*Less frequent:* Diarrhoea, abdominal pain.

##### Hepato-biliary disorders:

*Less frequent:* Hepatotoxicity.

##### Skin and subcutaneous tissue disorders:

*Less frequent:* Rash.

*Passiflora incarnata:*

##### Nervous system disorders:

*Less frequent:* Sedation, dizziness, ataxia, delirium.

##### Cardiac disorders:

*Less frequent:* Prolonged QT interval, tachycardia.

##### Gastrointestinal disorders:

*Less frequent:* Nausea, vomiting.

##### 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:  
<http://www.sahpra.org.za/Publications/Index/8>.

#### 4.9 Overdose

In an overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).  
In the event of overdose, treatment should be symptomatic and supportive.

### 5. PHARMACOLOGICAL PROPERTIES

#### Category and class:

D 33.6 Complementary Medicine: Western Herbal Medicine

#### 5.1 Pharmacodynamic properties

*Valeriana officinalis*

Valerians anxiolytic, anticonvulsant, and sedative properties may be due to the effects of its constituents on gamma-aminobutyric acid (GABA), adenosine A1, and serotonin (5HT) receptors. Valerenic acid and other constituents of valerian are GABA-agonists. Valerian constituents may inhibit the enzyme system responsible for the central catabolism of GABA, increasing GABA concentrations and decreasing CNS activity. Valerian may also bind directly to GABA-A receptors and stimulate the release and reuptake of GABA. In addition to the effects on GABA, valerian might affect sleep regulation via activity on adenosine and serotonin (5-HT1) receptors.

*Passiflora incarnata*

Data suggest that passion flower inhibits uptake of gamma-aminobutyric acid (GABA) into neuronal synapses, and has affinity for GABA(A) and GABA(B) receptors.

#### 5.2 Pharmacokinetic properties

*Valeriana officinalis*

Maximum valerenic acid serum concentrations usually occur within 1 – 2 hours. The elimination half-life of valerenic acid is about 1.1 hours.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

##### Core:

Di-calcium phosphate  
Magnesium stearate  
Microcrystalline cellulose  
Sodium starch glycolate

##### Film Coating (Flexicoat Protective Peach Pink):

FD&C Red 40 Alum Lake  
FD&C Yellow 6 Alum Lake  
Kollicoat IR  
Kowet Titanium Dioxide  
Sincovit Black  
Talc Pharma B98

#### 6.2 Incompatibilities

Not applicable.

#### 6.3 Shelf Life

24 Months.

#### 6.4 Special precautions for storage

Store at or below 25 °C and protect from moisture.

#### 6.5 Nature and contents of container

White 175 ml PET bottle with a white screw on cap and induction seal, containing a silica gel desiccant and foam wadding.  
Pack size: 60 tablets.

#### 6.6 Special precautions for disposal

No special requirements.

### 7. HOLDER OF CERTIFICATE OF REGISTRATION

PhytoHealthcare (Pty) Ltd.  
49 New Road  
Block C  
Midrand  
1685

### 8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

### 9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

<b>JOB:</b> BPS_Stress Relief (60's) PI		<b>SIZE:</b> 246mm x 215mm	
<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>COLOUR:</b> <div><div></div>K</div>		<b>FINISHING:</b> <div><input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing</div>	
<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.			