

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Hypromellose (capsule shell)

### 6.2 Incompatibilities

Not Applicable.

### 6.3 Shelf-life

3 years.

### 6.4 Special Precautions for storage

Store below 25°C in the original package.

### 6.5 Nature and contents of container

Duma 110ml HDPE plastic container and tamper evident threaded Duma cap.

VALDRIAN pack contains 60 Capsules.

### 6.6 Special precautions for disposal

There are no special precautions for disposal of VALDRIAN capsules. When the container is empty the label should be removed and the container placed in a recycling bin.

## 7 MARKETING AUTHORISATION HOLDER

Bio-Health Limited  
Culpeper Close  
Medway City Estate  
Rochester  
Kent  
ME2 4HU

## 8 MARKETING AUTHORISATION NUMBER(S)

THR 15817/0004

## 9 DATE OF REGISTRATION

11/07/2008

## 10 DATE OF REVISION

09/12/2009



# Valdrian®

## SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

## 1 NAME OF THE MEDICINAL PRODUCT

VALDRIAN Capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 400mg of Valerian root. (*Valeriana officinalis* L.)

For list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Hard capsules.  
Clear size 0 hard capsules.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

VALDRIAN is a traditional herbal medicinal product used for the temporary relief of symptoms of mild anxiety and to aid sleep, based on traditional use only.

### 4.2 Posology and method of administration

For oral short term use only.  
Adults and the elderly.

For the temporary relief of symptoms of mild anxiety take one capsule 3 times daily swallowed with water.  
To aid sleep, take one capsule 30 minutes before bedtime with an earlier dose during the evening if necessary.

As treatment effects may not be apparent immediately, VALDRIAN should be taken 2-4 weeks continuously.  
Maximum daily dose:- 4 single doses.

Duration of use:-  
If symptoms persist, worsen or do not improve after 4 weeks during the use of VALDRIAN a doctor or a qualified healthcare care practitioner should be consulted.

Not recommended for children or adolescents under 18 years.

### 4.3 Contra-indications

Patients with known hypersensitivity to Valerian root should not use VALDRIAN.

### 4.4 Special Warnings and Precautions for Use

The use of this product is not recommended in children and adolescents below the age of 18 years.

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

Only limited data on pharmacological interactions with other medicinal products are available. Clinically relevant interactions with drugs metabolised by the CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 pathway has not been observed. Additive effects with hypnotics and other sedatives cannot be excluded and therefore comedication is not recommended as a general precaution.

The effect of Valerian may be potentiated by alcohol. Excessive concomitant consumption of alcohol should therefore be avoided.

## 4.6 Pregnancy and Lactation

The safety of VALDRIAN during pregnancy and lactation has not been established. Due to the lack of data, use during pregnancy and lactation is not recommended.

## 4.7 Effects on ability to drive and use machines

VALDRIAN may impair ability to drive and use machines.  
Patients who are affected should not drive or operate machinery.

## 4.8 Undesirable effects

Gastrointestinal symptoms (eg nausea, abdominal cramps) may occur after ingesting VALDRIAN (valerian root). The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or qualified health care practitioner should be consulted.

## 4.9 Overdose

Valerian root at a dose of approximately 20g (equivalent to 50 VALDRIAN capsules) caused benign symptoms (fatigue, abdominal cramp, chest tightness, light headedness, hand tremor and mydriasis), which disappeared within 24 hours. If symptoms arise, treatment should be supportive.

After intake of very high doses of Valerian root over several years (daily consumption corresponding to approximately 30g of the drug) withdrawal symptoms (delirium) have been reported.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Hypnotics and sedatives, ATC Code: NO5C MO9

Not Applicable.

### 5.2 Pharmacokinetic Properties

No data available.

### 5.3 Preclinical safety data

Extracts with ethanol and the essential oil of Valerian root have shown low toxicity in rodents during acute tests and from repeated dose toxicity over periods of 4-8 weeks.  
Test on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.