

Herbal TABLETS With extracts of Hop Strobile, Valerian and Passion Flower

# Read all of this leaflet carefully before you take this product because it contains important information you need to know.

This product is available without prescription; however, you still need to use this product carefully to get the best results from it. Keep this leaflet as you may need to read it again. Ask your doctor, pharmacist or qualified healthcare practitioner if you need more information or advice.

### In this leaflet:

- 1. What this product is and what it is used for.
- 2. Before you take this product.
- 3. How to take this product
- 4. Possible side effects.
- 5. How to store this product.
- 6. Further information.

## 1. What this product is and what it is used for

- This medicine contains extracts of:
- hop strobile
- valerian root
- passion flower herb.

A traditional herbal medicinal product used for the temporary relief of sleep disturbances based on traditional use only.

## 2. Before you take this product

## **Do not** take this product if you are:

allergic to any of the ingredients (see section 6)
under 18 years of age
already taking a medicine that makes you sleepy, or for stress or anxiety.

# Pregnancy and breast feeding

Do not take this product if you are pregnant or breast feeding, because there is no evidence that it is safe to do so.
The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.

# Driving and using machinery

• These tablets may make you feel sleepy or dizzy. If affected do not drive or operate machines.

FRONT

## **3. How to take this product**

For oral use. Swallow the tablets whole with water. Do not chew.

Adults and the elderly: 2 tablets 1 hour before you go to bed. Not recommended for use in children or adolescents under 18 years old.

As the effects of this product may not occur immediately, it should be taken continuously for 2 – 4 weeks. If symptoms worsen or persist after 4 weeks consult your doctor, pharmacist or qualified healthcare practitioner.

Do not take more medicine than the leaflet tells you to. P26367' LF23224C

#### What to do if too many tablets are taken

If you take too many tablets by mistake, contact your doctor or pharmacist straight away and take this leaflet with you.

### **4. Possible side effects**

Like all medicines, this product can have side-effects, although not everybody gets them.

The following side effects have been reported with Valerian root preparations:

• Nausea (feeling sick) • Vomiting

Abdominal Cramps
 Dizziness

Abdominal pain
 Headache

Diarrhoea
 Nightmares or vivid dreams
 If these persist for more than a few days or become troublesome,
 stop taking this product.

#### Other side effects:

One case of hypersensitivity (vasculitis) and one case of increased heartbeat (tachycardia) have been reported in patients using Passion Flower herb.

If you are concerned about any side effect, if a side effect becomes serious or if you notice a side effect not listed in this leaflet, please tell your doctor or qualified healthcare practitioner.

### Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the **Yellow Card Scheme** at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store this product** Keep out of the sight and reach of children.

Do not use these tablets after the expiry date printed on the pack.

Do not store above 25°C. Store in the original package.

#### **6. Further information** Each film coated tablet contains the active ingredients:

34 mg of extract (as dry extract) from Hop strobile (*Humulus lupulus* L.) (4-6:1). Extraction solvent: Methanol 30% (v/v),

30.8 mg of extract (as dry extract) from Valerian root (*Valeriana officinalis* L.) (4.5-6:1). Extraction solvent: Ethanol 60% (v/v),

18.2 mg of extract (as dry extract) of Passion Flower herb (*Passiflora incarnata* L.) (3-7:1) Extraction solvent: Ethanol 70% (v/v).

#### The other ingredients are:

Extract excipients: Maltodextrin, colloidal anhydrous silica.

**Core excipients:** Calcium hydrogen phosphate, microcrystalline cellulose, stearic acid, magnesium stearate.

Film-coating: Polyethylene glycol 400, hypromellose 4500, hydroxypropylmethyl cellulose, iron oxides (E172), titanium dioxide (E171).

This product is available in pack sizes of 6, 20, 24, 30, 48, 50, 60, 90 and 120 tablets. Not all pack sizes are marketed. This product is a tan brown, circular biconvex, film coated tablet.

#### Is this leaflet hard to see or read?

Contact us on: Telephone: +44 (0)1283 228300 Email: info@bruhealth.co.uk

**THR Holder & Manufacturer is:** Brunel Healthcare Manufacturing Ltd., William Nadin Way, Swadlincote, Derbyshire, DE11 0BB, U.K.

P26367

LF23224C

Text revised: September 2023

THR: 20894/0073

