

THR 23056/0009

Bonuit Sleep Aid Tablets

MHRA approved leaflet (01.04.2014)

6: Further information

Each coated tablet of this product contains 125mg of extract (as dry extract) from Valerian root (*Valeriana officinalis* L.) (3-6:1) (equivalent to 375-750mg of Valerian root). Extraction solvent: Ethanol 70%v/v; **and** 250mg of extract (as dry extract) from Passion Flower herb (*Passiflora incarnata* L) (5-7:1) (equivalent to 1250-1750mg of Passion Flower herb). Extraction solvent Ethanol 50%v/v.

This product also contains the following ingredients:

Tablet core: Maltodextrin, silica colloidal anhydrous, cellulose powdered, croscarmellose sodium, magnesium stearate, stearic acid, talc, liquid glucose.

Coating: Sucrose, talc, calcium carbonate (E170), acacia, tragacanth, titanium dioxide (E171), liquid glucose, iron oxide hydrate (E172), hypromellose, white beeswax, carnauba wax, shellac.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

Each coated tablet contains 32mg of glucose and 187mg of sucrose.

Each pack contains 14, 15, 28 or 30 coated tablets.

Not all sizes may be marketed.

Registration holder for this product

Schwabe Pharma (UK) Ltd
Alexander House, Mere Park,
Dedmere Road, Marlow, Bucks SL7 1FX



Certification
Mark

Manufacturer of this product

Wiewelhove GmbH,
Gildestrasse 39, 49477 Ibbenbüren, Germany

Traditional herbal registration number: THR 23056/0009

If you would like further information about this product, please contact:

Schwabe Pharma (UK) Ltd
Alexander House, Mere Park, Dedmere Road, Marlow, Bucks SL7 1FX

Telephone: 01628 401980 Email: info@schwabepharma.co.uk

This leaflet was revised 01/2013

For a large print, Braille or audio version of this leaflet, call 01628 401980

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Patient Information Leaflet

Bonuit® Sleep Aid tablets

Valerian root extract 125mg and Passion Flower herb extract 250mg

Please read this leaflet carefully before you start taking these tablets.

It contains some important information about Bonuit Sleep Aid.

Keep this leaflet with the tablets.

You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet

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1: What this product is and what it is used for

This product is a traditional herbal medicinal product containing Valerian root and Passion Flower herb. Each coated tablet of this product contains 125mg of extract (as dry extract) from Valerian root (*Valeriana officinalis* L.) (3-6:1) (equivalent to 375-750mg of Valerian root). Extraction solvent: Ethanol 70%v/v; **and** 250mg of extract (as dry extract) from Passion Flower herb (*Passiflora incarnata* L) (5-7:1) (equivalent to 1250-1750mg of Passion Flower herb). Extraction solvent Ethanol 50%v/v.

Bonuit Sleep Aid is a traditional herbal medicinal product used for the temporary relief of sleep disturbances due to symptoms of mild anxiety. This usage is based on traditional use only.

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2: Before you take this product**DO NOT TAKE this product if you are:**

- **under 18 years of age**
- **pregnant or breast-feeding**
- **allergic to any of the ingredients** (see section 6)
- **already taking other medicines for sleep or anxiety**

Tell your doctor before taking this product if you have an intolerance to some sugars (see section 6). **The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.**

3: How to take this product**Adults and the elderly**

Take 1 to 2 tablets half an hour before bedtime. If necessary, an additional tablet can be taken earlier in the evening. Swallow the tablets whole with some water or other liquid. Do not chew the tablets.

As the effects of this product may not occur immediately, the tablets should be taken continuously for 2–4 weeks.

Do not exceed the stated dose.

If you take too much of this product (overdose)

If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product

Continue to take your usual dose at the usual time; it does not matter if you have missed a dose.

If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4: Possible side-effects

Like all medicines, this product can have side-effects. These are listed below.

Side-effects

- | | |
|--|---|
| <ul style="list-style-type: none"> ● abdominal cramps ● nausea | If these persist for more than a few days, or become troublesome, stop taking this product. |
|--|---|

Other side-effects

There has been one report of tachycardia (increased heart beat) and one report of hypersensitivity (vasculitis) in patients using Passion Flower herb. Tell your doctor or pharmacist if you notice any other side-effect not mentioned in this leaflet.

This product may cause drowsiness. If you are affected do not drive or operate machines.

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your GP's surgery or pharmacy, or call Freephone 0800 100 3352 (available 10am–2pm Monday – Friday).

You must speak to a qualified healthcare practitioner if your symptoms worsen, if they do not improve after four weeks, or if side-effects not mentioned in this leaflet occur.

5: How to store this product

Do not use your tablets after the expiry date.

Return any out-of-date tablets to your pharmacist who will dispose of them for you. The expiry date is printed on the box and the blister pack.

Store the tablets in a cool dry place.

Do not store the tablets in a place where the temperature goes above 30°C.

Keep the tablets out of the reach and sight of children.

Keep your tablets in the blister pack until it is time to take them.