

SOMINEX HERBAL

With extracts of Hop Strobile, Valerian, Passion Flower

Patient Information Leaflet

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.

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

This medicine contains extracts of:

- hop strobile
- valerian root
- passion flower herb

These tablets are a traditional herbal medicinal product used for the temporary relief of sleep disturbances based on traditional use only.

2. Is this product suitable for you?

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 for sleep 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 might cause drowsiness which can persist into the following day. If affected do not drive or operate machinery.

Each tablet contains glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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 exceed the stated dose.

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.

What to do if you miss a dose

If you miss a dose just take the next dose when it is due. Do not take a double dose to make up for the missed dose.

4. Possible side effects

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

The frequency of the side effects is not known.

The following side effects have been reported:

- Gastrointestinal symptoms such as nausea (feeling sick) and stomach cramps have been reported with Valerian root preparations

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 all medicines out of the reach and sight 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: Ethanol 70% (v/v)

30.8 mg of extract (as dry extract) from Valerian root (*Valeriana officinalis* L.) (4:1)

Extraction solvent: Ethanol 60% (v/v)

15.2 mg of extract (as dry extract) of Passion Flower herb (*Passiflora incarnata* L.)

(5-7:1) Extraction solvent: Ethanol 50% (v/v)

The other ingredients are:

Extract excipients: Maltodextrin, colloidal anhydrous silica, liquid glucose.

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 a pack size of 30 tablets.

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.

The Distributor is Actavis UK Ltd, Barnstaple, EX32 8NS, UK.

