

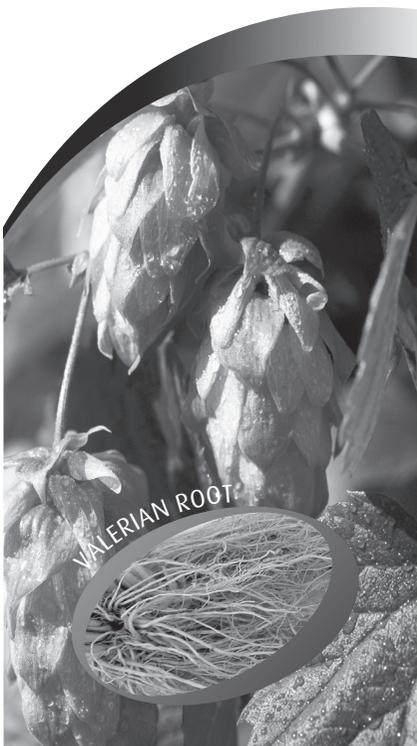


Patient Information Leaflet

A.Vogel

**Dormeasan®
Sleep**

Valerian-Hops oral drops



Information

Important things you need to know

- This product is used for the temporary relief of sleep disturbances resulting from mild anxiety.
- This product is suitable for adults over 18 years. It is not known to be habit forming.
- **Don't take** this product if you are allergic to any of the ingredients: see section 6.
- **Don't take** this product if you are already taking another medicine to help you sleep or for anxiety.
- **Before you take this product:** read section 2.
- **Dosage instructions:** see section 3.
- **Talk to your doctor** if your symptoms worsen or you do not feel any benefit from this product within 4 weeks.
- Side effects are minor: see section 4.

Now read the rest of this leaflet carefully. Keep this leaflet. You may need to read it again.

1. What this product is for

Dormeasan Sleep is a traditional herbal medicinal product used for the temporary relief of:

- Sleep disturbances resulting from mild anxiety

This is based on traditional use only.



Do's & Don'ts

2. Before you use this product

Do not take this product:

- If you are under 18 years of age.
- If you are already taking another medicine to help you sleep or for anxiety.
- If you are taking another medicine which is affected by alcohol.
- If you are allergic to any of the ingredients in this product (see section 6 Further Information).
- If you are pregnant or breast-feeding.

You should also know

- This medicinal product contains 62 vol % ethanol (alcohol), i.e. up to 420 mg per 30 drop dose, equivalent to 11 ml beer (less than a tablespoon) or 4 ml wine (less than a teaspoon) per dose.
- If you suffer from alcoholism the alcohol content of this product may be harmful.
- If you are in a high-risk group (patients with liver disease or epilepsy) you should consider the alcohol content before taking this product.



Using

3. How to use this product

Adults and the elderly:

To aid sleep: Take 30 drops in a little water or fruit juice half an hour before bedtime.

This product may also be used to relieve the symptoms of mild anxiety: Take 10–20 drops in a little water or fruit juice once or twice daily.

Do not take more than 70 drops a day.

The effects of this product may not be felt immediately. You may need to take it for up to 4 weeks for best results.

Don't take more than the recommended dose.

This product is not known to be habit forming.



Using

If you take too much

- If you feel ill, talk to your doctor. Taking too much is unlikely to be harmful.
- Overdose of this product may result in alcohol intoxication and should be treated accordingly (See section 2 You should also know).

If you forget to take this product

- Don't worry about the missed dose. Take the next dose as usual.

If you feel this product isn't working

- See your doctor if your symptoms worsen or do not improve within 4 weeks.

You can get a larger print or audio version of this leaflet.
Call this number:
0845 608 5858.



Side effects

4. Possible side effects

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

Minor side effects

The following minor side effects can occur when using this product.

- Feeling sick
- Stomach discomfort

These are often short-lived and should go away by themselves. However if they are troubling you, talk to your doctor or pharmacist.

If you are concerned about any side effect or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Driving and using machines

- This product is intended to help you fall asleep. If you feel drowsy do not drive or operate machinery.
- The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.



Information

5. How to store this product

- Keep out of the reach and sight of children.
- Do not use this product after the expiry date on the packaging. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Do not use this product if you notice a change in colour. It should be a clear liquid that is greenish brown in colour.

6. Further Information

What this product contains

1 ml of oral liquid contains:

Valerian root tincture 0.5 ml

(*Valeriana officinalis* L.) (1:10-11)
Extraction solvent: ethanol 58% V/V

Hops strobile tincture 0.5 ml

(*Humulus lupulus* L.) (1:12-13)
Extraction solvent: ethanol 65% V/V

1 ml of Dormeasan Sleep is equivalent to 35 drops.

The other ingredients used for the liquid are ethanol and water.

What this product looks like and the contents of the pack

Dormeasan Sleep is a clear liquid that is greenish brown in colour. Dormeasan Sleep is available in 15 ml, 30 ml, 50 ml and 100 ml bottles. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder and Manufacturer

Traditional Herbal Registration Holder and Batch Release:

Bioforce (UK) Ltd,
2 Brewster Place,
Irvine, Ayrshire, UK
KA11 5DD

Manufacturer:

Bioforce AG, CH-9325, Roggwil
Switzerland

THR No. 13668/0017



Certification Mark

This leaflet was revised on 02/2012

What is Valerian?

Valerian is a flowering plant which is native to Europe and parts of Asia. It is the extract of Valerian roots which is used to make Dormeasan Sleep.

What are Hops?

Hops are flowering plants native to the Northern Hemisphere. Each plant produces either male or female flowers. The extract of the female flowers (commonly called Hops) is used to make Dormeasan Sleep.

You should also know

Bioforce runs a helpline by phone and email which can provide you with further information.

Email: enquiries@avogel.co.uk

Phone: 0845 608 5858

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 doctor's surgery or pharmacy, or call freephone 0808 100 3352 (available 10am-2pm Monday-Friday).