

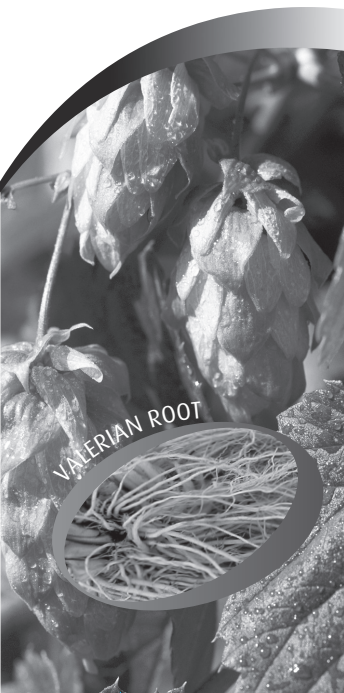


Package Leaflet:
Information for the user

A.Vogel

Dormesean®
Sleep

Valerian-Hops oral drops
Tinctures of fresh Valerian & Hops



pharma code

Information

Read all of this leaflet carefully before you start taking this product because it contains important information for you.

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

What is in this leaflet

1. What Dormesean Sleep is and what it is used for
2. What you need to know before you take Dormesean Sleep
3. How to take Dormesean Sleep
4. Possible side effects
5. How to store Dormesean Sleep
6. Contents of the pack and other information

1. What Dormesean Sleep is and what it is used for

Dormesean Sleep is a traditional herbal medicinal product containing the tinctures of fresh Valerian root and fresh Hop strobiles.

It is used to aid sleep. This is exclusively based on long-standing use.

Dormesean Sleep is for use in adults.

Do's and Don'ts

2. What you need to know before you take Dormesean Sleep

Do not take Dormesean Sleep

- If you are allergic to any of the ingredients of this product (listed in section 6).

Warnings and precautions

- See your doctor if your symptoms worsen or do not improve within 2 weeks

Children and adolescents

- Do not give this product to children or adolescents under 18 years of age as it is not known if it is suitable for them.

Other medicines and Dormesean Sleep

- Do not take this product if you are already taking another medicine which can cause drowsiness.
- Do not take this product if you are taking a medicine which is affected by alcohol.
- If you are speaking to your doctor, pharmacist or nurse always remember to tell them about any medicines you are taking, including herbal remedies such as Dormesean Sleep.

Pregnancy and breast-feeding

- Do not take this product if you are pregnant or breast-feeding as it may not be suitable for you.

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.

- This product contains alcohol (see below for alcohol content). Overdose of this product may result in alcohol intoxication.

Dormesean Sleep contains alcohol

- 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.
- Harmful for those suffering from alcoholism.
- To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

Using

3. How to take Dormesean Sleep

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Recommended dose

Adults and older people: Take 30 drops in a little water or fruit juice half an hour before bedtime.

The effects of this product may not be felt immediately. You may need to take it for up to 2 weeks for best results. For oral short-term use only.

Do not take more than the recommended dose.

If you take more Dormesean Sleep than you should

- If you take too much and feel ill, talk to your doctor.
- Overdose of this product may result in alcohol intoxication and should be treated accordingly.



Using

If you forget to take Dormeasan Sleep

- Do not worry about a missed dose, take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product ask your doctor, pharmacist or nurse.



Side effects

4. Possible side effects

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

Side effects

Digestive symptoms

- Feeling sick
- Stomach pains

Stop taking this product if you find these are troubling you. Talk to a doctor or pharmacist if you are concerned.

The frequency of these side effects is not known. This means it is not known how often these side effects occur as there have not been enough reports to allow this information to be calculated.

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:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517

Website: www.hpra.ie
E-mail: medsafety@hpra.ie

- By reporting side effects you can help provide more information on the safety of this medicine.



Information

5. How to store Dormeasan Sleep

- Keep this product out of the sight and reach of children.
- Do not use this product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- This product does not require any special storage conditions.
- Do not use this product if you notice a change in appearance. It should be a clear liquid that is greenish-brown in colour.
- Do not throw any medicines away via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dormeasan Sleep contains

30 drops of oral liquid contains:

Valerian root tincture 394 mg
(*Valeriana officinalis* L.) (1:10-11)
Extraction solvent: Ethanol 58% V/V

Hops strobile tincture 394 mg
(*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 Dormeasan Sleep looks like and 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 and 50 ml bottles. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder and Manufacturer

Bioforce (UK) Ltd,
2 Brewster Place,
Irvine, Ayrshire, KA11 5DD - UK
Tel: +44 (0)1294 277344
enquiries@avogel.co.uk

TR 725/5/1

This leaflet was last revised in 06/2016

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: **1 890 930 070**

You can get a larger print or audio version of this leaflet. Call this number: 1 890 930 070