

Package Leaflet: Information for the user



Valerian Complex

Stress Relief

oral drops

Tinctures of fresh Valerian & Hops



i 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

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

1. What Valerian Complex is and what it is used for

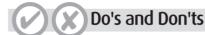
Valerian Complex is a traditional herbal medicinal product containing the tinctures of fresh Valerian root and fresh Hops strobile.

It is used for the relief of symptoms of:

Mild mental stress

This is exclusively based on longstanding use.

Valerian Complex is for use in adults.



2. What you need to know before you take Valerian Complex

Do not take Valerian Complex

 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 Valerian Complex

- 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 Valerian Complex.

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 relax. 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.

Valerian Complex contains alcohol

- This medicinal product contains 62 vol % ethanol (alcohol), i.e. up to 280 mg per 20 drop dose, equivalent to 7 ml beer (half a tablespoon) or 3 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.



3. How to take Valerian Complex

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 10-20 drops in a little water or fruit juice once or twice daily.

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 40 drops a day.

If you take more Valerian Complex than you should

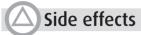
- If you take too much and feel ill, talk to your doctor.
- Overdose of this product may result in alcohol intoxication and should be treated accordingly.



If you forget to take Valerian Complex

- 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.



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

i Information

5. How to store Valerian Complex

- 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.
- Use within 5 months of opening.
- 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 away any medicines 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 Valerian Complex contains

20 drops of oral liquid contains:

Valerian root tincture 263 mg (*Valeriana officinalis* L.) (1:10–11) Extraction solvent: Ethanol 58% V/V

Hops strobile tincture 263 mg (*Humulus lupulus* L.) (1:12–13) Extraction solvent: Ethanol 65% V/V

1 ml of Valerian Complex is equivalent to 35 drops.

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

What Valerian Complex looks like and contents of the pack

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

Traditional Herbal Registration Holder

A.Vogel Ireland Ltd, 48 Upper Drumcondra Road, Dublin 9, Ireland Tel: 1 890 930 070 enquiries@avogel.ie

Manufacturer

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

TR 2309/020/001

This leaflet was last revised in 02/2019.

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 Valerian Complex.

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 Valerian Complex.

You should also know

A.Vogel Ireland runs a helpline by phone and email which can provide you with further information.

E-mail: enquiries@avogel.ie Phone: 1 890 930 070

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