Package leaflet: Information for the user

VADRIAN Hard Capsules

VALDRIAN ROOT 400mg 60 CAPSULES

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

You must talk to a doctor if you feel worse while taking this product or do not feel better after 2 weeks.

What is in this leaflet

- 1. What Valdrian is and what it is for
- 2. What you need to know before you take Valdrian
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1. What Valdrian is and what it is for

The active herbal ingredient in each capsule of Valdrian is Valerian root.

Valdrian is a traditional herbal medicinal product for relief of symptoms of mild mental stress and to aid sleep, exclusively based on long-standing use.

You must talk to a doctor if you feel worse while taking this product or do not feel better after 2 weeks.

2. What you need to know before you take Valdrian

Do not take :

If you are allergic to Valerian root or any of the other ingredients of this medicine (listed in section 6). If you are pregnant or breastfeeding, If you are under 18 years of age.

Children and adolescents

Valdrian should not be used in children and adolescents under 18 years.

Other medicines and Valdrian

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including other herbal medicines or medicines that didn't require a prescription.

The effects of this product may be increased by some medication. Consult your doctor or pharmacist before taking Valdrian if you are also taking other mediciation which causes drowsiness.

Pregnancy, breast-feeding and fertility

Do not take this product if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, as it is not known if it is safe to do so.

Valdrian with alcohol

The effects of Valdrian may increased by alcohol. Excessive use of alcohol should therefore be avoided.

Driving and using machines

Valdrian may impair ability to drive and use machines. Patients who are affected should not drive or operate machinery.

3. How to take Valdrian

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your pharmacist if you are not sure. The recommended dose is:

Dosage

Swallow the capsules whole with water. Do not chew the capsules.

Adults and elderly:

Take 1 capsule 3 times daily swallowed with water, or to aid sleep take 1 capsule 30 minutes before bedtime, with an additional dose earlier in the evening if necessary. Maximum daily dose 4 capsules. **This product is not suitable for children under 18 years old.**

If you take more Valdrian than you should

If you take more than the recommended dose, see a doctor or pharmacist and take this leaflet with you.

If you are unsure about anything relating to Valdrian

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

4. **Possible Side effects**

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

Nausea or abdominal cramps have been known to occur from taking Valerian root preparations such as Valdrian. The frequency is not known.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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, 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.

5. How to store Valdrian

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the label and carton after "Expiry Date". The expiry date refers to the last day of that month.

Do not throw away any medicines via 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 Valdrian contains:

Each hard capsule of Valdrian contains the following active herbal ingredient:

400mg of *Valeriana officinalis L.*, radix minutata (Cut valerian root). The capsule shell is made from hypromellose.

What Valdrian looks like and contents of the pack

The capsules are hard, clear, oblong and contain a light brown powder. Each pot of Valdrian contains 60 capsules.

Traditional Herbal Registration Holder and Manufacturer

Traditional Herbal Registration Holder for Valdrian: **HUK Europe Ltd.** 28/30 Burlington Road, Dublin 4, D04 HR90, Ireland.

Manufacturer: **Bio-Health Ltd.** Culpepper Close, Medway City Estate, Rochester, Kent, ME2 4HU, United Kingdom.

Traditional Registration number:

TR25313/001/001

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