

The other ingredients/excipients are:

Lactose monohydrate, dextrin, colloidal silica, micro-crystalline cellulose, cellulose powder, sodium-carboxymethyl starch (type A), stearic acid (Ph. Eur.), magnesium stearate (Ph. Eur.), poly[butylmethacrylate-co-(2-dimethyl-aminoethyl) methacrylate-co-methyl methacrylate] (1:2:1), sucrose (saccharose), talc, calcium carbonate, arabic gum, tragacanth, poly(O-acetyl) starch, montanglycol wax, titanium dioxide.

6.2 What Ardeysedon® Nacht looks like and contents of the pack

Appearance

White, round, shiny coated tablets

Packs

Packs with 20, 50, and 100 coated tablets.

6.3 Marketing authorisation holder and manufacturer

Ardeypharm GmbH, Loerfeldstraße 20, 58313 Herdecke, Germany
www.ardeypharm.de

This leaflet was last approved in July 2013.

Dear Patient!

It is possible that the leaflet in your medicine pack may differ from this version. This leaflet is an internal, unofficial translation of the German package leaflet and may not apply to other countries.

Package Insert Leaflet: information for the user

Ardeysedon® Nacht

Coated tablets

For use in adults and adolescents

Active substances: Dry extract of valerian root, Dry extract of hop strobile



Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to take Ardeysedon® Nacht carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve within 14 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What is Ardeysedon® Nacht and what is it used for?
2. What must be observed before taking Ardeysedon® Nacht?
3. How to take Ardeysedon® Nacht?
4. Possible side effects.
5. How to store Ardeysedon® Nacht?
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1. What is Ardeysedon® Nacht and what is it used for?

Ardeysedon® Nacht is used with episodes of restlessness and problems falling asleep caused by nervousness.

2. Before you take Ardeysedon® Nacht

2.1 Do not take Ardeysedon® Nacht

If you are hypersensitive (allergic) to the active ingredients or any of the other ingredients of Ardeysedon® Nacht.

2.2 Take special care with Ardeysedon® Nacht

In case problems falling asleep caused by nervousness persist longer than 2 weeks or worsen, you must definitely consult a doctor.

The experience in children is limited. Therefore, Ardeysedon® Nacht is not recommended for use in children below age 12.

2.3 Taking other medicines

There is only limited data on the pharmacological interactions of valerian-hops preparations with other medicines available. Interactions with other medicines are not known so far.

However, the combination with synthetic sedatives is not recommended.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

2.4 Taking Ardeysedon® Nacht with food and drink

Avoid drinking alcohol when using Ardeysedon® Nacht.

2.5 Pregnancy and breast-feeding

Widespread use of valerian root and hop strobile as drugs has not indicated risks and side effects during pregnancy and lactation so far. However, there is no experience from experimental studies. Therefore, Ardeysedon® Nacht is not recommended for use during pregnancy and lactation.

2.6 Driving and using machines

Do not drive, operate machines, or work without secure footing up to 2 hours after taking Ardeysedon® Nacht, because your ability to react may be impaired even with intended use. This effect is intensified by the effects of alcohol.

2.7 Important information about some of the ingredients of Ardeysedon® Nacht

Ardeysedon® Nacht contains lactose and sucrose (sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ardeysedon® Nacht

Always take Ardeysedon® Nacht exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

3.1 Dosage

Unless otherwise directed by your doctor, the usual dose to adults and adolescents from 12 years of age applies:

- For the treatment of episodes of restlessness take 1 coated tablet up to 3 times daily.
- For the treatment of problems falling asleep caused by nervousness take 1 coated tablet ½ to 1 hour before going to bed. If necessary, you may take 1 coated tablet in the course of the evening already in addition.

3.2 Method of administration

Take orally.

Do not take Ardeysedon® Nacht in a horizontal position.

Use sufficient liquid (preferentially a glass of water) and do not chew the coated tablets.

3.3 Duration of treatment

In principle, the duration of Ardeysedon® Nacht administration is not limited.

However, please notice the information under point 2.2.

Please consult your doctor or pharmacist whenever you get the impression of the effect of Ardeysedon® Nacht being too strong or too weak.

3.4 If you take more Ardeysedon® Nacht than you should

If you take twice or three times the recommended dose of Ardeysedon® Nacht by mistake (corresponding to 2-3 coated tablets), this normally has no adverse consequences. In this case continue taking Ardeysedon® Nacht as is stated in this leaflet or suggested by your doctor.

If you overdose Ardeysedon® Nacht considerably, consult a doctor.

3.5 If you forget to take Ardeysedon® Nacht

Do not take a double dose to make up for a forgotten dose. Continue taking Ardeysedon® Nacht as is stated in this leaflet or suggested by your doctor.

If you have further questions regarding the use of the medicine, please ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Ardeysedon® Nacht can cause side effects, although not everybody gets them.

This list comprises all known side effects under treatment with valerian root and hop strobiles, even those under higher dosage or long-term therapy.

For the assessment of side effects, the following data on frequency are used as a basis:

Very common:	More than 1 of 10 patients treated
Common:	More than 1 of 100 patients treated
Uncommon:	More than 1 of 1,000 patients treated
Rare:	More than 1 of 10,000 patients treated
Very rare:	1 or less of 10,000 patients treated, or unknown

4.1 Possible side effects

Very rarely, allergic skin reactions may occur.

Normally side effects already disappear on discontinuation of Ardeysedon® Nacht.

If you notice first signs of a hypersensitivity reaction, do not take Ardeysedon® Nacht again. After use of preparations from valerian root, gastro-intestinal complaints (e.g. nausea, abdominal cramps) may occur. The frequency is not known.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

4.2 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 Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ardeysedon® Nacht

Keep out of the reach and sight of children.

Do not use Ardeysedon® Nacht after the expiry date which is stated on the carton and on the blister.

Storage conditions:

Do not store above 25 °C!

6. Further Information

6.1 What Ardeysedon® Nacht contains

The active substance is:

1 coated tablet contains:

200 mg dry extract from valerian root with the drug/dry extract from valerian root ratio as (4–7:1)

The extraction solvent is Ethanol 70% (V/V).

and

68 mg dry extract from hop strobile with the drug/dry extract from hop strobile ratio as (4–8:1)

The extraction solvent is Ethanol 40% (V/V).