

# Valerian and Hop

# **Coated tablets**

Medicinally active substances: dry extract of valerian root 160 mg, dry extract of hop strobile 40 mg
For application of adults and adolescents as of 12 years of age.

Please read the whole package information sheet / directions for use through carefully as they contain important information for you.

This medicinal product is also obtainable without a medical prescription. To achieve the best possible therapeutic success, Cirkulin Valerian and Hop coated Tablets must however be taken in accordance with the instructions.

- Keep the package information sheet. You may perhaps wish to read this again later.
- Ask your pharmacist if you need any further information or advice.
- If your symptoms worsen or there is no improvement after 14 days, you must consult a doctor.
- If one of the specified side effects it substantially impaired or you notice side effects, which are not indicated in this
  customs information, inform please your doctor or pharmacist.

# This package information sheet contains:

- 1. What are Cirkulin Valerian and Hop coated Tablets and what are they used for?
- 2. What must you pay attention to before taking Cirkulin Valerian and Hop coated Tablets?
- 3. How are Cirkulin Valerian and Hop coated Tablets to be taken?
- 4. What side effects are possible?
- 5. How must Cirkulin Valerian and Hop coated Tablets be stored?
- 6. Further information

# 1. WHAT ARE CIRKULIN VALERIAN AND HOP COATED TABLETS AND WHAT THEY ARE USED FOR?

Cirkulin Valerian and Hop coated Tablets are a plant-based medicinal product for sedation. Therapeutic indications:

Cirkulin Valerian and Hop coated Tablets are used in cases of states of restlessness and difficulty in falling asleep due to

# 2. WHAT MUST YOU PAY ATTENTION TO BEFORE TAKING CIRKULIN VALERIAN AND HOP COATED TABLETS?

Cirkulin Valerian and Hop coated Tablets must not be taken:

If you are hypersensitive (allergic) to the medicinally active substances, azorubin dye (E122) or of the other constituents. Special caution when taking Cirkulin Valerian and Hop coated Tablets is necessary Children:

No adequate investigations exist with regard to the application of this medicinal product in children. Therefore it is not recommended that this medicinal product is taken by children under 12 years of age.

Interactions with other medicinal products:

Interactions with other medicinal products and incompatibility are none known.

Please inform your doctor or pharmacist if you are taking/using other medicinal products or have recently taken/used such products, even if it is not a question of medicinal products that are only obtainable on prescription.

When taking Cirkulin Valerian and Hop coated Tablets together with food and drink

While using this medicinal product, as far as possible you should not drink alcohol.

Pregnancy and lactation:

To date, from the widespread use of valerian root as a medicinal product there have been no indications for risks during pregnancy and lactation, however no results of experimental investigations exist. You should therefore not take this medicinal product during pregnancy and lactation.

# Effects on ability to drive and to use machines:

Up to 2 hours after taking this medicinal product you should not drive a motor vehicle, operate a machine or carry out work without safe support as your reaction capability may be impaired even when the product is taken in accordance with instructions. This applies even more so in combination with alcohol.

Important warnings with regard to certain other constituents of the medicinal product:

Azorubin dye (E 122) may bring about hypersensitivity reactions.

This medicinal product contains saccharose (sucrose) and lactose. Therefore please only take Cirkulin Valerian and Hop coated Tablets after consultation with your doctor if you know that you suffer from sugar intolerance.

# 3. HOW ARE CIRKULIN VALERIAN AND HOP COATED TABLETS TO BE TAKEN?

Always take Cirkulin Valerian and Hop coated Tablets exactly in accordance with the instructions in this package information sheet. Please ask your doctor or pharmacist if you are not quite sure.

Unless otherwise prescribed by the doctor, the usual dose is:

For adults and adolescents from 12 years of age.

- to treat states of restlessness 2 tablets up to 3 times daily.
- to treat difficulty in falling asleep due to nervousness 2 tablets ½ to 1 hour before retiring. If necessary, you can
  additionally take 2 tablets earlier in the evening.

# Method of administration:

For internal application.

Do not take coated tablets in the lying position.

Please swallow the tablets whole with plenty of liquid (preferably a glass of drinking water).

# Duration of application:

The period during which you can take this medicinal product is in principle unlimited.

If the symptoms last longer than 2 weeks or worsen, you must in any case consult a doctor.

Please consult your doctor or pharmacist if you have the impression that the effect of this medicinal product is too strong or too weak.

## If you have taken a larger quantity of Cirkulin Valerian and Hop coated Tablets than you should:

If you have at any time inadvertently taken double or triple the prescribed dose (corresponds to 4-6 coated tablets of medicinal product), as a rule this has no negative consequences. In this case continue to take the tablets as described in the dosage instructions or as was prescribed by your doctor.

If you have taken a substantial overdose of this medicinal product, you should consult a doctor.

If you have forgotten to take Cirkulin Valerian and Hop coated Tablets:

Do not take a double dose but continue to take or apply the tablets as stated in this package information sheet or prescribed by your doctor.

Should you have further questions for applications of the medicinal preparation please ask your doctor or pharmacist.

# 4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicinal products, this medicinal product can have side effects which do not have to arise however with everyone. The list includes all known side effects with the treatment of valerian root and hop strobile, including those that may occur at a higher dosage or in a long-term therapy.

When evaluating side effects, the following frequencies are taken as the basis:

Very frequent: More than 1 in 10 people treated	Frequent: Less than 1 in 10, but more than 1 in 100 treated
Occasional: less than 1 in 100, but more than 1 in 1000 people treated	Rare: less than 1 in 1000, but more than 1 in 10,000 people treated
Very rare: 1 or fewer of 10,000 people treated including isolated instances	

### Possible side effects:

In very rare cases allergic skin reactions may occur.

Azorubin dye (E 122) may bring about hypersensitivity reactions.

As a rule discontinuing the use of the medicinal product is sufficient to cause the side effects to disappear again.

At the first signs of a hypersensitivity reaction, this medicinal product should not be taken again.

Inform your doctor or pharmacist if you notice any side effects that are not listed in this package information sheet.

# 5. HOW MUST CIRKULIN VALERIAN AND HOP COATED TABLETS BE STORED

Store medicines out of reach of children.

You must no longer use the medicinal product after the expiry date stated on the surrounding carton or container. The expiry date refers to the last day of the month.

Do not store at over 25 °C and keep the tablets in the original packing in order to protect the contents against humidity.

# 6. FURTHER INFORMATION

What contains Cirkulin Valerian and Hop coated Tablets?

The medicinally active substances:

1 coated tablet contains: 160 mg dry extract of valerian root in a relationship of drug to extract of 4-6:1, the extraction agent is water and 40 mg dry extract of hop strobile in a relationship of drug to extract of 3-6:1, the extraction agent is water.

The other constituents are:

Sucrose (saccharose), talcum, maltodextrin, microcrystalline cellulose, lactose, calcium carbonate, macrogol 6000, purified water, stearic acid, spray dried gum arabic, spray dried glucose syrup, highly disperse silicon dioxide, silicon dioxide, methylated, methyl acrylic acid-ethyl acryliate-copolymer (1:1) dispersion 30%, colours azorubin (E 122) and titanium dioxide (E 171), magnesium stearate, montan glycol wax, polysorbate 20, polysorbate 80.

# What Cirkulin Valerian and Hop coated Tablets look like and contents of the pack:

Cirkulin Valerian and Hop coated Tablets are obtainable in packs containing 20 and 40 coated tablets.

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