

PACKAGE LEAFLET: INFORMATION FOR THE USER

Valemont - coated tablets

Active substance: valerian root extract

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 *Valemont - coated tablets* carefully to get the best results from them.

- 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 after 2 weeks.
- 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 *Valemont - coated tablets* are and what they are used for
2. Before you take *Valemont - coated tablets*
3. How to take *Valemont - coated tablets*
4. Possible side effects
5. How to store *Valemont - coated tablets*
6. Further information

1. WHAT VALEMONT - COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Valemont - coated tablets are a herbal medicine with sedative and tension-relieving properties for promoting the readiness for sleep.

Valemont - coated tablets are used for problems in falling and staying asleep.

2. BEFORE YOU TAKE VALEMONT - COATED TABLETS

Do not take *Valemont - Coated Tablets*

- if you are allergic (hypersensitive) to *valerian root extract* or any of the other ingredients of *Valemont - coated tablets*.

Taking other medicines

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

If other synthetic sleeping pills or sedatives are taken at the same time, the effects may be mutually enhanced. This combination requires medical diagnosis and supervision.

Taking *Valemont - coated tablets* with food and drink

The effect of *valerian root preparations* may be enhanced if large amounts of alcohol are consumed at the same time.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

As there are no adequate data for the use of *valerian root extract* during pregnancy and breast-feeding, its use is not recommended during this time.

Driving and using machines



Warning: This medicine may impair responsiveness and the ability to drive.

Even when used as directed, taking this medicine may alter responsiveness to such an extent as to impair ability to drive or use machines. You must not drive any vehicles or use any tools or machines. This applies particularly in combination with alcohol.

Important information about some of the ingredients of *Valemont - Coated Tablets*

This medicine contains lactose (milk sugar), glucose (grape sugar) and sucrose (beet sugar). For this reason, if you have been told that you have an intolerance to some sugars, please contact your doctor before taking *Valemont - coated tablets*.

3. HOW TO TAKE *VALEMONT - COATED TABLETS*

Always take *Valemont - coated tablets* exactly as directed in this leaflet. You should check with your doctor or pharmacist if you are not sure.

For adults and adolescents over 12 years of age, the usual dose is:

1-2 coated tablets, 30 minutes to 1 hour before going to bed.

If needed, an extra 1-2 coated tablets earlier in the evening.

Maximum daily dose: 4 tablets.

Method of administration:

The coated tablets should be taken whole (not chewed) with a sufficient amount of alcohol-free liquid (e.g. 1 glass of water).

Duration of use:

Valemont - coated tablets are not suitable for acute short-term use, as the maximum effect is not reached until after 2-4 weeks with continued intake.

If symptoms persist or get worse after taking *Valemont* for 2 weeks, a doctor should be consulted.

Children:

Use in *children below 12 years* is not recommended, as no adequate studies are available.

If you take more *Valemont - coated tablets* than you should

To date, there have been no reported cases of overdose with *Valemont - coated tablets*.

Valerian root at a dose of approximately 20 g (equivalent to about 67 coated tablets) caused symptoms (fatigue, abdominal cramp, chest tightness, lightheadness, hand tremor and mydriasis), which disappeared within 24 hours. If symptoms arise, consult a doctor.

If you forget to take *Valemont - coated tablets*

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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, *Valemont - coated tablets* can cause side effects, although not everybody gets them.

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.

Gastrointestinal complaints, such as nausea and abdominal cramps, have been observed after *valerian root extracts* have been taken. It is not known how often such complaints occur.

If hypersensitivity reactions occur, treatment must be discontinued and a doctor consulted.

5. HOW TO STORE *VALEMONT - COATED TABLETS*

Do not store above 30°C.

Store in the original package in order to protect from light and moisture.

Keep out of the reach and sight of children.

Do not use *Valemont - coated tablets* after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What *Valemont - coated tablets* contain

- The active substance is: *valerian root extract*
Each coated tablet contains 300 mg of extract (as dry extract) from *Valeriana officinalis* L.s.l., radix (Valerian root) (DER = 3-6:1, extraction solvent: Ethanol 70% V/V).
- The other ingredients are:
Core: spray-dried glucose syrup, silica, cellactose 80 (cellulose, lactose monohydrate), sodium starch glycollate, stearic acid, talc.
Coating: sucrose, talc, gum arabic, Eudragit E12.5, methylcellulose, calcium carbonate, povidone K30, silica, glycerol 85%, iron oxide/hydroxide brown and red (E172), montan glycol wax.

What *Valemont - coated tablets* look like and contents of the pack

Brown coated tablets.

Blisters of 20 tablets, together with the package leaflet in an outer carton.

Marketing Authorisation Holder and Manufacturer

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