

Package leaflet: information for the user

Sedacur[®] forte Beruhigungsdragees

coated tablets

for application in adults and adolescents from the age of 12 years
dry extracts of valerian roots, hop strobiles and balm leaves

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 Sedacur[®] forte Beruhigungsdragees 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 after 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.

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1. What Sedacur[®] forte Beruhigungsdragees is and what it is used for

Sedacur[®] forte Beruhigungsdragees is a herbal medicine for sedation.

Sedacur[®] forte Beruhigungsdragees is used in case of restlessness and nervously determined difficulties in falling asleep.

2. Before you take Sedacur[®] forte Beruhigungsdragees

2.1 Do not take Sedacur[®] forte Beruhigungsdragees

if you are hypersensitive (allergic) to the active ingredients valerian root, hop strobile, balm leaves or any of the other ingredients (see under 6. "Further information") of Sedacur[®] forte Beruhigungsdragees.

2.2 Take special care with Sedacur[®] forte Beruhigungsdragees,

if your complaints persist for more than 2 weeks or worsen. Then you should consult a doctor in any case.

2.3 Children

No sufficient investigations are available for the use of this medicine in children. Therefore, the use of this medicine is not recommended for children younger than 12 years.

2.4 Taking other medicines

Up to now no interactions with Sedacur[®] forte Beruhigungsdragees are known.

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

2.5 Taking Sedacur[®] forte Beruhigungsdragees with food and drink

During the intake of this medicine you should not drink alcohol, if possible.

2.6 Pregnancy and breast-feeding

The common use of valerian root, hop strobile, balm leaves as a medicine shows up to now no indication regarding risks during pregnancy and lactation. However, results of experimental investigations are not available. Therefore, you should **not** take Sedacur[®] forte Beruhigungsdragees during pregnancy and breast-feeding.

2.7 Driving and using machines

Up to 2 hours after the intake of this medicine you should not drive machines, operate machinery or work without secure halt, since your reactivity can be influenced, even if taken as directed. This effect may be enhanced especially by consumption of alcohol.

2.8 Important information about some of the other ingredients of Sedacur[®] forte Beruhigungsdragees

This medicine contains the sugars glucose and sucrose. Please only take Sedacur[®] forte Beruhigungsdragees after talking with your doctor, if you know that you suffer from an intolerance to certain sugars.

3. How to take Sedacur[®] forte Beruhigungsdragees

Always take Sedacur[®] forte Beruhigungsdragees exactly as directed in this package leaflet. Please check with your doctor or pharmacist if you are not sure.

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

for adults and adolescents over 12 years

- for the treatment of restlessness
2 to 3 times daily 2 Sedacur[®] forte Beruhigungsdragees
- for the therapy of nervously determined difficulties in falling asleep
2 Sedacur[®] forte Beruhigungsdragees ½ to 1 hour before bedtime.

Do not take Sedacur[®] forte Beruhigungsdragees in horizontal position. Please take Sedacur[®] forte Beruhigungsdragees unchewed with sufficient liquid (preferably a glass of drinking water).

3.2 Duration of use

The duration of use of this medicine is not limited in principle. However, please consider the note under item 2.2.

Please ask your doctor or pharmacist if you have the impression that the effect of Sedacur® forte Beruhigungsdragees is too strong or too weak.

3.3 If you take more Sedacur® forte Beruhigungsdragees than you should

If you have inadvertently taken the double or triple dosage than described (corresponds to 4 – 6 Sedacur® forte Beruhigungsdragees), this has normally no adverse consequences. In this case continue the intake as described in the dosage instruction or as prescribed by your doctor.

If you have taken extremely more Sedacur® forte Beruhigungsdragees, you should contact a doctor.

3.4 If you forget to take Sedacur® forte Beruhigungsdragees:

Do not take a double dose, but continue the intake at the usual time.

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

4. Possible side effects

Like all medicines, Sedacur® forte Beruhigungsdragees can cause side effects, although not everybody gets them.

The listing includes all known side effects under the treatment with the active ingredients hop strobile and balm leaves, even those under higher dosage or long-term therapy.

Assessment of side effects is based on the following frequency rates:

very common:	more than 1 treated patient of 10
common:	1 to 10 treated patients of 100
uncommon:	1 to 10 treated patients of 1,000
rare:	1 to 10 treated patients of 10,000
very rare:	less than 1 treated patient of 10,000
unknown:	frequency not assessable on the basis of the available data

Possible side effects:

Rare: gastro-intestinal complaints.

Very rare: allergic skin reactions.

In general, the side effects disappear after stopping the medication.

If first signs of a hypersensitivity reaction occur, this medicine is not allowed to be taken again.

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 (...the national reporting system). By reporting side effects you can help to provide more information on the safety of this medicine.

5. How to store Sedacur® forte Beruhigungsdragees

Keep out of the reach and sight of children.

You should not use Sedacur® forte Beruhigungsdragees after the expiry date printed on the side flap of this pack. The expiry date refers to the last day of that month.

Do not store above 30°C.

6. Further information

What Sedacur® forte Beruhigungsdragees contains:

Active substances:

1 coated tablet contains

75 mg dry extract of valerian roots in a drug to extract ratio as 5–6 : 1,
the extractant is ethanol 70% (V/V)

23 mg dry extract of hop strobiles in a drug to extract ratio as 4–8 : 1,
the extractant is methanol 40% (V/V)

45 mg dry extract of balm leaves in a drug to extract ratio as 4–6 : 1,
the extractant is water.

The other ingredients are:

maltodextrin, colloidal anhydrous silica, microcrystalline cellulose, stearic palmitic acid, talc, povidone, copovidone, sucrose (saccharose), titanium dioxide E 171, maize starch, glucose syrup, carnauba wax, bleached wax, shellac, carboxymethylcellulose sodium, polysorbate 80, indigotine E132.

What Sedacur® forte Beruhigungsdragees looks like and contents of the pack:

The coated tablets are round with light blue glossy coating.

Sedacur® forte Beruhigungsdragees is available in packs containing 30, 60 and 100 coated tablets.

Marketing authorisation holder and manufacturer

Schaper & Brümmer GmbH & Co. KG

Bahnhofstraße 35

38259 Salzgitter

Germany

Tel: (0 53 41) 3 07-0

Fax: (0 53 41) 3 07-124

info@schaper-bruemmer.de

<http://www.schaper-bruemmer.com>

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