

PACKAGE LEAFLET: INFORMATION FOR THE USER

PERSEN

film-coated tablets

VALERIAN DRY EXTRACT; DRY EXTRACT OF LEMON BALM LEAF; DRY EXTRACT OF MINT LEAF

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What PERSEN is and what it is used for
2. Before you take PERSEN
3. How to take PERSEN
4. Possible side effects
5. How to store PERSEN
6. Further information

1. WHAT PERSEN IS AND WHAT IT IS USED FOR

PERSEN is a traditional herbal medicine used for the relief of mild symptoms of mental stress (such as mental tension and discomfort) and help with insomnia.

PERSEN is a traditional herbal medicine, and the stated range of applications is based on long-term use.

2. BEFORE YOU TAKE PERSEN

Do not take PERSEN in case of

- If you are allergic to valerian, lemon balm, peppermint (Mentha), menthol or any of the other ingredients.
- If you have inflammation of the bile ducts (cholangitis), gallstones or any other disorder related to the bile that requires professional medical supervision.

Take special care with PERSEN in

Please read this leaflet carefully before you start taking this medicine, even if you've already used it, because some of the information from the previous instructions could, in the meantime, change.

The application of PERSEN tablets are not recommended in children under 12 years.

If you suffer from gastroesophageal reflux disease you should avoid mint leaves, due to a possible reinforcement of heartburn.

If you have gallstones, or are suffering from any disease of the gallbladder and bile duct, be especially careful when taking products containing mint leaves.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. Only limited data on pharmacological interactions with other medicines are available. There were no clinically significant interactions with medicines metabolized by CYP 2D6, CYP 3A4 / 5, CYP 1A2 or CYP 2E1 enzymes.

Due to precautionary measures, it is not recommended to take tablets PERSEN with other sedatives or sleeping pills.

Consult your doctor or pharmacist if you are unsure whether you can take tablets PERSEN.

If you have any further questions on the use of PERSEN tablets, contact your doctor or pharmacist.

Taking food and drink with PERSEN tablets

Peresen tablets can be taken regardless of food.

While taking PERSEN it is not recommended to use alcohol because it can affect the action of PERSEN.

Pregnancy and breast-feeding

The safety of tablet PERSEN during pregnancy and breastfeeding has not been established and this is why its use in pregnant women and nursing mothers is not recommended.

Driving and using machines

PERSEN may have a negative impact on the ability to drive and use machines. During taking of the medicine it is not recommended to drive and use machines.

Other warnings

PERSEN tablets contain lactose, sucrose, glucose. If your doctor once said that you are allergic to some sugars, consult with him/her or with the pharmacist before you start taking the tablets PERSEN.

3. HOW TO TAKE PERSEN

Adults and children over 12 years

Alleviation of the mild symptoms of mental stress: 3 tablets of PERSEN three times a day.

Insomnia: 3 tablets of PERSEN half an hour to 1 hour before going to sleep with an earlier dose taken during the evening if necessary.

The maximum permitted daily dose: 4 individual doses.

PERSEN tablets are intended for oral use (orally).

Tablets should be swallowed with a small amount of water, regardless of the meal.

If during the two weeks of application PERSEN tablets health condition does not improve or gets worse, consult a doctor.

Use of the tablet PERSEN is not recommended in children younger than 12 years.

If you take more PERSEN than you should

Contact your doctor if you have taken higher dose than recommended.

A single dose of about 20 g of valerian root (Valerian) (approximately 103 tablets of PERSEN), may cause effects such as fatigue, abdominal cramps, feeling of pressure in the chest, dizziness, hand tremors and mydriasis (dilated pupils). If symptoms worsen or last longer than 24 hours, be sure to contact your doctor.

There is no data on overdose on balm (melissa) or peppermint (Mentha) leaf.

If you forget to take PERSEN chewable tablets

Do not take a double dose to make up for the forgotten tablet.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

After administration of preparations containing valerian root (Valerian) one may experience side effects of the digestive system such as nausea or abdominal cramps. The frequency of these side effects is not known.

There is a possibility of deterioration of gastroesophageal reflux disease after the application of peppermint (possibility of worsening of heartburn).

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE PERSEN

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use PERSEN after the expiry date which is stated on the label.

Medicines should not be disposed of via waste water 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 PERSEN contains

Active ingredients:

35 mg dry extract of Valeriana officinalis L., radix (valerian root), extraction solvent: ethanol 70% V / V (the ratio of herbal drug and the extract is 4-7: 1);

17.5 mg dry extract of Melissa officinalis L., folium (nursery list), extraction solvent: ethanol 50% V / V (the ratio of herbal drug and the extract is 3-6: 1);

17.5 mg dry extract of Mentha piperita L., folium (mint leaves); the extraction solvent: ethanol 40% V / V (the ratio of herbal drug and the extract is 3-6: 1).

Dry extracts do not contain alcohol.

The other ingredients are:

Core: glucose, liquid, maltodextrin, silica, colloidal anhydrous, peppermint flavor, lactose monohydrate, microcrystalline cellulose, corn starch, croscovidone, talc, magnesium stearate.

Coating: Hypromellose, carmellose, crospovidone, sucrose, silica colloidal anhydrous, calcium carbonate, iron oxide, brown (E172), titanium dioxide (E171), glycerol, talc, montan glycol wax.

What PERSEN looks like and contents of the pack

Persen tablets are round, bi-convex-coated, chocolate brown color.
40 (4x10) coated tablets in (Al / PVC / TE / PVDC) blisters, in a box.

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

Lek Pharmaceuticals dd, Verovškova 57, Ljubljana, Slovenia.