Package leaflet: Information for the user

Natures Aid Sleepeeze Valerian tablets Valerian root extract

Read all this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

What is in this leaflet:

- 1. What Natures Aid Sleepeeze is and what it is used for.
- 2. What you need to know before you take Natures Aid Sleepeeze.
- 3. How to take Natures Aid Sleepeeze.
- 4. Possible side effects.
- 5. How to store Natures Aid Sleepeeze.
- 6. Contents of the pack and other information.

1. WHAT NATURES AID SLEEPEEZE IS AND WHAT IT IS USED FOR.

Natures Aid Sleepeeze is a traditional herbal medicinal product used for the relief of mild mental stress and to aid sleep exclusively based on long standing use.

Each film-coated tablet contains 150mg of extract (as dry extract) from Valerian root (*Valeriana officinalis* L.) equivalent to 750-900mg of Valerian root. Extraction solvent: ethanol 70%v/v. You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NATURES AID SLEEPEEZE. Do not take Natures Aid Sleepeeze if:

- You are allergic to Valerian root or any of the other ingredients of this traditional herbal medicinal product listed in section 6.
- You are already taking medicine which can cause drowsiness
- You are pregnant or breastfeeding

Warnings and precautions.

- Do not exceed the stated dose.
- This product contains glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

Tell your doctor if your symptoms worsen <u>during use</u> or persist after you have taken Natures Aid Sleepeeze for 2 weeks.

Children and adolescents.

This product is not suitable for patients under 18 years of age.

Other medicines and Natures Aid Sleepeeze.

Tell your doctor or pharmacist if you are taking or have recently taken any other medication including herbal medicines or medicines that didn't need a prescription. **Do not** take this product if you are already taking a medicine which can cause drowsiness.

Natures Aid Sleepeeze with food and drink and alcohol.

• The effect of this product may be increased by alcohol, excessive use of alcohol should therefore be avoided.

Pregnancy and breast-feeding and fertility.

Do not take this product if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, as it is not known if it is safe to do so.

Driving and using machines.

This product may cause drowsiness. If you are affected, do not drive or operate machines.

Natures Aid Sleepeeze contains Glucose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

3. HOW TO TAKE NATURES AID SLEEPEEZE.

For oral short-term use only.

Always take Natures Aid Sleepeeze exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

The recommended dose is:

Adults and the elderly:

For relief of mild symptoms of mental stress, take one or two tablets daily.

To aid sleep, one tablet to be taken 30-60 minutes before bedtime. One additional tablet can be taken earlier in the evening if necessary.

Maximum dose: 3 tablets per day

As treatment may not be apparent immediately, the tablets should be taken continuously for 2 weeks. If symptoms worsen, persist or do not improve after 2 weeks, a qualified healthcare professional e.g. a doctor or a pharmacist should be consulted.

Use in children and adolescents:

Not recommended for children or adolescents under 18 years.

If you take more Natures Aid Sleepeeze than you should.

If you take more than the recommended dose (overdose), speak to a qualified healthcare professional e.g. a doctor or a pharmacist immediately and take this leaflet with you.

If you forget to take Natures Aid Sleepeeze.

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

Take the next dose when it becomes due.

If you stop taking Natures Aid Sleepeeze.

There are no reported adverse effects associated with stopping this product, but if you feel unwell talk to your doctor or qualified healthcare professional.

4. POSSIBLE SIDE EFFECTS.

Like all medicines, this product can cause side effects, although not everybody gets them. The frequency of side effects is not known. Possible minor, side effects include:

- abdominal cramps
- nausea

If you find these effects troublesome, stop using the product. Speak to your doctor or pharmacist if you are at all concerned, if a side effect becomes serious, or you notice an effect not mentioned in this leaflet.

Reporting of side effects.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance,

Website: www.hpra.ie

5. HOW TO STORE NATURES AID SLEEPEEZE.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original packaging.

Do not use this medicine if you notice any discolouring or softening of the tablets, as this means they may have deteriorated.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION.

What Natures Aid Sleepeeze contains.

Each tablet contains 150mg of extract (as dry extract) from Valerian root ($Valeriana\ officinalis\ L.$). Equivalent to $750-900mg\ Valerian\ root$.

Extraction solvent: Ethanol 70%v/v.

It also contains other, non-active, ingredients.

These ingredients are:

maltodextrin, colloidal anhydrous silica, calcium hydrogen phosphate, cellulose microcrystalline, colloidal hydrated silica. croscarmellose sodium, magnesium stearate, lecithin, glucose monohydrate, sodium citrate, dextrin.

What Natures Aid Sleepeeze looks like and contents of the pack.

Natures Aid Sleepeeze are brown, circular, convex film coated tablets and are available in packs of 30, 60 or 90 tablets (not all packs may be marketed).

Marketing Authorisation Holder and Manufacturer.

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