Read all of this leaflet carefully before you start taking this product because it contains important information for you. Always take this product exactly as described in this leaflet or as your doctor, 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, pharmacist or nurse. 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 AvenaCalm is and what it is used for
2. What you need to know before you take AvenaCalm
3. How to take AvenaCalm
4. Possible side effects
5. How to store AvenaCalm
6. Contents of the pack and other information

1. What AvenaCalm is and what it is used for
AvenaCalm is a traditional herbal medicinal product containing the expressed juice from fresh oat herb. It is used for the temporary relief of symptoms of:
- Mild mental stress
- To help sleep
This is exclusively based on long-standing use.
AvenaCalm is for use in adults.

2. What you need to know before you take AvenaCalm
Do not take AvenaCalm
- If you are allergic to any of the ingredients of this product (listed in section 6).

Warnings and precautions
- See your doctor before taking this product if you suffer from coeliac disease. The protein content of this product is not known.
- See your doctor if your symptoms worsen or do not improve within 2 weeks, or if new symptoms develop.

Children and adolescents
Do not give this product to children or adolescents under 18 years of age.

3. How to take AvenaCalm
Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Recommended dose
Adults (18 years and over): For mild mental stress
Take 25-30 drops in a little water before bedtime.

Do not take more than 90 drops a day.
For oral short-term use only.

If you take more AvenaCalm than you should
- If you take too much and feel ill, talk to your doctor.

4. Possible side effects
Pregnancy and breast-feeding
- Do not take this product if you are pregnant or breast-feeding.

Driving and using machines
- This product is intended to help you relax. If you feel drowsy do not drive or operate machinery.
- The effects of this product may be increased by alcohol. Excessive use of alcohol should therefore be avoided.

The product contains alcohol (see below for alcohol content). Overdose of this product may result in alcohol intoxication.

AvenaCalm contains alcohol
This medicinal product contains 51 vol % ethanol (alcohol), i.e. up to 328 mg per 30 drop dose, equivalent to 8 ml beer (less than a tablespoon) or 3 ml wine (less than a teaspoon) per dose.
Harmful for those suffering from alcoholism.
To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

5. How to store AvenaCalm
- Store AvenaCalm in a cool place out of the reach of children.
- Do not use AvenaCalm after the expiry date shown on the pack.
- The product may turn brown over time. This is due to the natural content of colouring matter in the product and does not affect its efficacy.

6. Contents of the pack and other information
- Each pack contains 100 drops of AvenaCalm.

Do’s and Don’ts
- Do not take this product if you are pregnant or breast-feeding.
- Do not take this product while driving or operating machinery.
- Do not take this product if you are already taking a medicine which is affected by alcohol.
- Do not take this product while sleeping.

Expressed juice from oat herb
Avena sativa
oral drops
Ex pressed juice from oat herb

Using
Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Recommended dose
Adults (18 years and over): For mild mental stress
Take 25-30 drops in a little water before bedtime.

Do not take more than 90 drops a day.
For oral short-term use only.

If you take more AvenaCalm than you should
- If you take too much and feel ill, talk to your doctor.

Overdose of this product may result in alcohol intoxication and should be treated accordingly.

Please turn over...
If you forget to take AvenaCalm
Do not worry about a missed dose. Take the next dose as usual.
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, pharmacist or nurse.

4. Possible side effects
No side effects have been reported with the use of products containing Avena sativa extract.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse.
You can also report side effects directly via:
HPRA Pharmacovigilance
Earlfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store AvenaCalm
Keep this product out of the sight and reach of children.
Do not use this product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
Use within 4 months of opening.
This product does not require any special storage conditions.
Do not use this product if you notice a change in appearance.
It should be a clear liquid that is yellow-brown to green-brown in colour. Very small pieces of herbal material may be visible.
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 AvenaCalm contains
30 drops contains 381 mg of expressed juice from fresh oat herb (Avena sativa L.) in ethanolic solution. 1 ml of AvenaCalm oral drops is equivalent to 37 drops. The other ingredients used for the liquid are ethanol (alcohol) and water.

What AvenaCalm looks like and contents of the pack
AvenaCalm is a clear liquid that is yellow-brown to green-brown in colour. Very small pieces of herbal material may be visible. AvenaCalm is available in 50 ml and 100 ml brown bottles. Not all pack sizes may be marketed.