

PATIENT INFORMATION LEAFLET

AvenaCalm ***Avena sativa***

oral drops

Expressed juice from oat herb

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.

Other medicines and AvenaCalm

- Do not take this product if you are already taking a medicine which is affected by alcohol.
- If you are speaking to your doctor, pharmacist or nurse always remember to tell them about any medicines you are taking, including herbal remedies such as AvenaCalm.

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

AvenaCalm contains alcohol

- This medicine contains 328 mg of alcohol (ethanol) in each 30 drop dose.
- The amount in each dose (30 drops) of this medicine is equivalent to less than 9 ml beer or 4 ml wine.
- The small amount of alcohol in this medicine will not have any noticeable effects.

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 twice daily.

This product may also be used **to help sleep:** Take 30 drops in a little water half an hour 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.

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
Earlsfort 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.

Traditional Herbal Registration Holder

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What is *Avena sativa*?

Avena sativa is more commonly known as oats. It is the expressed juice from the above-ground parts of the plant which is used to make AvenaCalm.

You should also know

A.Vogel Ireland runs a helpline by phone and email which can provide you with further information.

E-mail: enquiries@avogel.co.uk

Phone: 0818 930 070

You can get a larger print or audio version of this leaflet. Call this number: 0818 930 070.