Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

AvenaCalm Avena sativa oral drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

30 drops contains 381 mg of expressed juice from *Avena sativa* L., herba rec. (fresh oat herb) in ethanolic solution.

1 ml is equivalent to 37 drops.

Excipients with known effect:
A maximum dose of 30 drops contains approximately 328 mg of ethanol (alcohol).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution (oral drops)
Clear yellow-brown to green-brown liquid which may contain a fine precipitation.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the temporary relief of symptoms of mild mental stress and to aid sleep exclusively based on long-standing use.

4.2 Posology and method of administration

Posology

Adults (18 years and over):
For relief of symptoms of mild mental stress:
Take 25-30 drops twice daily.

To aid sleep:
Take 30 drops in a little water half an hour before bedtime.

Maximum daily recommended dose is 90 drops.

Not recommended for use in children and adolescents under 18 years (see Section 4.4 Special warnings and precautions for use).

Do not exceed the stated dose.

Duration of use

If symptoms persist, worsen or do not improve after 2 weeks a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Method of administration

For oral short-term use only.

4.3 Contraindications

Do not use in cases of known hypersensitivity to Oats, Oat preparations or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.

If symptoms persist, worsen or do not improve after 2 weeks, or if new symptoms develop whilst taking this medicinal product, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Caution is advised when used in patients with coeliac disease because data on the protein content is not available.

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.

4.5 Interaction with other medicinal products and other forms of interaction

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole).

4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established, therefore the use of this product during pregnancy and lactation should be avoided.

Studies on fertility have not been performed.

4.7 Effects on ability to drive and use machines

May impair ability to drive and use machines, affected patients should not drive or operate machinery.

This product contains alcohol (see Section 4.4. for details of alcohol content).

4.8 Undesirable effects

None known.

If adverse reactions occur, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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

4.9 Overdose

Overdose of this product may result in alcohol intoxication: the amount of alcohol in a full bottle (20.2 g in 50 ml: 40.4 g in 100 ml: equivalent to approximately 2 or 4 glasses of wine, respectively) may result in intoxication and should be treated accordingly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.3 Preclinical safety data

Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96% V/V)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years (unopened).
Use within 4 months of opening.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions

6.5 Nature and contents of container

Amber glass dropper bottles (Type III glass Ph. Eur.) with a tamper-proof screw cap (polypropylene), tamper ring (high density polyethylene), fitted with a drop inset dispenser (low density polyethylene).
Pack size: 50 ml

Amber glass dropper bottles (Type III glass Ph. Eur.) with a child-resistant closure (polypropylene cap with high density polyethylene child-resistant mechanism or high density polyethylene cap with a high density polyethylene child-resistant mechanism) fitted with a drop inset dispenser (low density polyethylene).
Pack sizes: 50 ml and 100ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 REGISTRATION HOLDER

A. Vogel Ireland Limited,
Unit 3D, Killeen Road,
Dublin 10
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8 REGISTRATION NUMBER(S)

TR2309/012/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 1st of July 2016
Date of last renewal: 30th June 2021

10 DATE OF REVISION OF THE TEXT

July 2022