

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Avena sativa comp oral drops solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml contains the ethanolic tinctures of:

Avena sativa L., Herba (1=2 in 30% w/w alcohol)	25.0 ml
Humulus lupulus L., Fruct. (1=10 in 86% w/w alcohol)	4.0 ml
Passiflora incarnata L., Herba (1=3 in 62% w/w alcohol)	7.5 ml
Valeriana officinalis L., Radix decoct. (1=10 in 43% w/w alcohol)	30.0 ml

Total content of ethanol: 45% v/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution.

A clear to slightly turbid amber-brown liquid, fine suspended particles may be present.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Traditionally used for relief of symptoms of restlessness, promoting relaxation and natural sleep at night.

4.2 Posology and method of administration

Over 12 years: Daytime use: 15-20 drops to be taken in water three times daily. Night-time use: 20-40 drops to be taken in water half an hour before retiring.

Elderly: The adult dose is appropriate.

Children: Not to be used in children under 12 years unless under the guidance of a medical practitioner.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

Consult your doctor or pharmacist if you are taking any other medication.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy: There is no evidence of the safety of the product in human pregnancy, nor is there any evidence from animal studies. Although no adverse reactions have been observed, the use of the product during pregnancy should be avoided unless under the guidance of a medical practitioner.

Lactation: There is no evidence to suggest that the product should not be used during lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

4.9 Overdose

No known data on overdose.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Herbal hypnotics and sedatives. ATC code: N5B5

5.2 Pharmacokinetic properties

No information in this area is presently available.

5.3 Preclinical safety data

This product has been marketed for over 50 years.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coffea arabica L., Semen tosta decoct. 60X homeopathic potency. 15.0 ml
Ethanol 90%
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Four years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

25 ml amber glass bottle fitted with a plastic dropper which dispenses approximately 0.021 ml per drop, and sealed with a white tamper-evident plastic screw cap closure.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Weleda (UK) Ltd
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8 MARKETING AUTHORISATION NUMBER

PA 407/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th October 1991

Date of last renewal: 11th October 2006

10 DATE OF REVISION OF THE TEXT

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