PROFESSIONAL INFORMATION FOR

Dormeasan

COMPLEMENTARY MEDICINE
Western Herbal Medicine
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
A.VOGEL DORMEASAN, oral drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 mL contains:

Humulus lupulus L. (Hop) [Fresh inflorescences, 1:12 extract providing dry plant equivalent: 38 mg per mL]	460 mg
Valeriana officinalis L. (Valerian) [Fresh root, 1:10 extract providing dry plant equivalent: 46 mg per mL]	460 mg

Contains 62 % *v/v* alcohol.

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Oral drops, solution (oral drops).
Clear, green to brown liquid with an odour of hop and valerian and a strong, bitter taste of hop.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
A.VOGEL DORMEASAN is a herbal medicine for the relief of sleep disturbances, and mild stress and anxiety.
The ingredients support the nervous system by having a calming action and address symptoms such as restlessness and anxiety and promote restful sleep.

4.2 Posology and method of administration
Posology

Adults and children over 12 years:
To promote restful sleep:
Take 30 drops half an hour to one hour before bedtime.
(May increase to 75 drops if necessary).
For daytime anxiety:
Take 10 – 20 drops once or twice daily.

Special populations
Elderly population:
No dosage adjustment is required for this population.

Paediatric population:
Children 6 – 12 years:
To promote restful sleep:
Take 10 drops half an hour to one hour before bedtime.
For daytime anxiety:
Take 5 – 10 drops once or twice daily.

Method of administration
For oral use only.
Take drops diluted in a small volume of water. It may be sweetened if required e.g. with honey or fruit juice.

4.3 Contraindications
- Hypersensitivity to the active substances, *Humulus lupulus* L. (Hop) and/or *Valeriana officinalis* L. (Valerian), or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
- If symptoms worsen or do not improve after 2 weeks of using A.VOGEL DORMEASAN, a doctor, pharmacist or other health care provider should be consulted.
- Do not exceed stated dose (see section 4.2).

Paediatric population
- A.VOGEL DORMEASAN is not recommended for use in children under 6 years of age.

Excipients with known effect
Contains alcohol:
- A.VOGEL DORMEASAN contains 489 mg (0,62 mL) of alcohol (ethanol) in each 1 mL which is equivalent to 62 % *v/v.*
- 10 drops A.VOGEL DORMEASAN contains 140 mg of alcohol (ethanol) which is equivalent to less than 4 mL beer or 2 mL wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- 30 drops A.VOGEL DORMEASAN contains 419 mg of alcohol (ethanol) which is equivalent to less than 11 mL beer or 5 mL wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- 75 drops A.VOGEL DORMEASAN contains 1 048 mg of alcohol (ethanol). This dose to an adult, weighing 70 kg would result in exposure to 15 mg/kg of alcohol which may cause a rise in blood alcohol concentration (BAC) of about 2,5 mg/100 mL which is equivalent to less than 27 mL beer or 11 mL wine. The dose to a 12 year old child, weighing 40 kg would result in exposure to 26,2 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 4,2 mg/100 mL, which is equivalent to 44 mL of beer or 18 mL of wine.
- A.VOGEL DORMEASAN can be harmful to those suffering from alcoholism, patients with liver disease or epilepsy.

4.5 Interaction with other medicines and other forms of interaction
Limited data on pharmacological interactions with other medicinal products are available.
- Clinically relevant interactions with drugs metabolised by the CYP 2D6, CYP 3A4/5, CYP 1A2 or CYP 2E1 pathway have not been observed.
- Additive effects with hypnotics and other sedatives cannot be excluded and therefore co-medication is not recommended.
- A .VOGEL DORMEASAN contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole) and/or medicines containing propylene glycol or ethanol (alcohol).

4.6 Fertility, pregnancy and lactation
Pregnancy
The safety of this product during pregnancy has not been established. In the absence of sufficient data, the use of A.VOGEL DORMEASAN during pregnancy is not recommended, unless advised by and under the supervision of a health care provider.

Breastfeeding
The safety of this product during breastfeeding has not been established.
In the absence of sufficient data, the use of A.VOGEL DORMEASAN during breastfeeding is not recommended, unless advised by and under the supervision of a health care provider.

Fertility
Fertility studies have not been performed.

4.7 Effects on ability to drive and use machines
A.VOGEL DORMEASAN may have an effect on mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision in sensitive individuals.

It is not always possible to predict to what extent A.VOGEL DORMEASAN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which A.VOGEL DORMEASAN affects them.

4.8 Undesirable effects
Tabulated list of adverse reactions

System Organ Class	Frequency	Adverse reactions
Immune system disorders	Frequency unknown	Hypersensitivity e.g. skin rash, hives, itching, fever, swelling, shortness of breath, wheezing and runny nose.
Gastrointestinal disorders	Frequency unknown	Nausea, abdominal cramps

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8.
In addition, side-effects can also be reported to info@pharmacorp.co.za.

4.9 Overdose
In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).
A.VOGEL DORMEASAN contains alcohol (see section 4.4) and according to the ingested amount of alcohol, an overdose may result in symptoms of intoxication. The amount of alcohol in a full bottle is 24,8 g in 50 mL and is equivalent to 1 large glass of wine.

Valerian root at a dose of approximately 20 g caused benign symptoms (fatigue, abdominal cramps, chest tightness, light-headedness, hand tremors and mydriasis), which disappeared within 24 hours.

No cases of overdose have been reported for Hops.

Treatment of overdosage should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Category and class: D33.6 Western Herbal Medicine
Pharmacotherapeutic group and ATC code: Hypnotics and sedatives / N05C M09

Mechanism of action
The sedative effects of preparations of valerian root, which have long been recognised empirically, have been confirmed in controlled clinical studies. Orally administered dry extracts of valerian root and Humulus lupulus (hops inflorescences) prepared with ethanol in the recommended dosage have been shown to improve sleep latency and sleep quality. These effects cannot be attributed with certainty to any known constituents.

5.2 Pharmacokinetic properties
Maximum serum concentration (C_{max}) is reached within 1 – 2 hours with valerenic acid (VA) (one of the constituents and markers of valerian root extracts) detectible at least 5 hours post dosing of 600 mg valerian root extract and the determined elimination half-life ($T_{½}$) is 1,1 ± 0,6 h. The area under the concentration time curve (AUC) is variable (4,80 ± 2,96 ug/mL h) and does not correlate with age or weight. The C_{max}, T_{max} and $T_{1/2}$ or area under the time curve (AUC) does not differ between a single 300 mg dose and that measured after 2 weeks of nightly dosing in elderly women. However C_{max} and AUC decreased, and $T_{1/2}$ increase with increased body weight.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Ethanol
Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months unopened.
Use within 5 months of opening.

6.4 Special precautions for storage
Store at or below 25 °C.
Store in the original package/container.
Keep the container tightly closed.

6.5 Nature and contents of container
Packed in an amber type III glass bottle, with plastic dropper (LDPE) and screw cap (HDPE) with tamper evident seal.
Pack size: 50 mL

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
PHARMACORP (PTY) LTD
29 Victoria Link
Route 21 Corporate Park
Irene, 0178, RSA

8. REGISTRATION NUMBER(S)
To be allocated.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
To be allocated.

10. DATE OF REVISION OF TEXT
September 2023

13141/PI/09.23