PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Neuroforce Formula

COMPLEMENTARY MEDICINE

Homeopathic Medicines

This unregistered medicine has not been evaluated by the South African Health Product Regulatory Authority for its quality, safety or intended use.

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

A.VOGEL NEUROFORCE FORMULA (oral drops)
Homeopathic Complex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Amorphous selenium *(Selenium metallicum)*	D12	0,07 ml
Anamirta cocculus L. Wight & Arn. *(Cocculus indicus)*	D6	0,07 ml
Asarum europaeum L. *(Asarum europaeum)*	D6	0,07 ml
Avena sativa L. *(Avena sativa)* Mother Tincture [HAB 1A]		0,07 ml
Cinchona pubescens Vahl *(China officinalis)*	D6	0,07 ml
Cypripedium parviflorum Salisb. L. var. *pubescens* (Willd.) O.W. Knight *(Cypripedium pubescens)*	D6	0,07 ml
Delphinium staphisagria L. (Staphisagria)	D6	0,07 ml
Hypericum perforatum L. / *Hypericum perforatum* L. ex Herba *(Hypericum perforatum)* Mother Tincture [HAB 3A]		0,07 ml
Metallic zinc *(Zincum metallicum)*	D12	0,07 ml
Passiflora incarnata L. *(Passiflora incarnata)* Mother Tincture [HAB 3A]		0,07 ml
Sepia officinalis L. (Common cuttlefish)	D12	0,07 ml
Strychnos ignatii Bergius *(Ignatia amara)*	D6	0,07 ml
Vitex agnus-castus L. *(Agnus castus)* Mother Tincture [HAB 4A]		0,07 ml
White phosphorus (Phosphorus)	D30	0,07 ml

Contains more than 50 % *v/v* alcohol.
Sugar free.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Light brown liquid, that may contain fine particles, with an aromatic odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL NEUROFORCE FORMULA is a homeopathic nerve tonic.
The ingredients specifically address nervous tension and exhaustion during or after stressful events with hypersensitivity, agitation and restlessness.
A.VOGEL NEUROFORCE FORMULA is indicated for emotional symptoms such as grief, tearfulness, anger, resentment, irritability, anticipation, fear and depressed mood.
It supports the nervous system during periods of stress, conflict or emotional strain; or to use in situations of acute shock and trauma.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:
Take 10 drops 4 times daily.
In acute/severe cases:
Take 10 drops hourly, gradually reducing frequency as improvement occurs, or as directed by a doctor, pharmacist or other healthcare provider.

Special populations

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

Paediatric population:
Children 6 – 12 years:
Take 5 drops 4 times daily.
Children 2 – 6 years:
Take 2 drops 4 times daily.
In acute/severe cases:
Take the relevant number of drops, as specified above for the child's age category, hourly, gradually reducing frequency as improvement occurs, or as directed by a doctor, pharmacist or other healthcare provider.

Method of administration

For oral use only.
Take drops on the tongue, or directly under the tongue, or in a teaspoon of water.
Take 15 minutes before meals.
Discontinue once improvement occurs.

4.3 Contraindications

- A.VOGEL NEUROFORCE FORMULA should not be used in patients who have a hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- A.VOGEL NEUROFORCE FORMULA contains alcohol and should be used with caution by individuals with a sensitivity or intolerance to alcohol.
- If symptoms worsen or do not improve after 2 weeks during the use of A.VOGEL NEUROFORCE FORMULA, a doctor, pharmacist or other healthcare provider should be consulted.

A.VOGEL NEUROFORCE FORMULA contains very small quantities of *Hypericum perforatum* L., St John's Wort, (0,07 ml / 1 ml) which, in substantially larger doses, is contraindicated with:
- Antiplatelets and anticoagulants, e.g. warfarin, phenprocoumon
- Calcium channel antagonists, e.g. nifedipine, verapamil
- Digoxin
- Finasteride
- HIV non-nucleoside transcriptase inhibitors, e.g. nevirapine
- HIV protease inhibitors, e.g. indinavir
- Immunosuppressants, e.g. cyclosporin, tacrolimus
- Methadone
- Oncology chemotherapeutics, e.g. irinotecan, imatinib

Use with caution and under medical supervision. No interactions are expected.
(Bone and Mills. 2013)

Hypericum perforatum L., St John's Wort, in substantially larger doses, should be used with caution and under medical supervision when co-administering the following medicine, which is not expected to be necessary under the recommended dosages for A.VOGEL NEUROFORCE FORMULA:
- Amitriptyline
- Anticonvulsants, e.g. carbamazepine, mephenytoin, phenobarbitone, phenytoin
- Antihistamines, e.g. fexofenadine
- Antiplatelets and anticoagulants, e.g. clopidogrel
- Benzodiazepines, e.g. alprazolam, midazolam, quazepam
- Hypoglycaemic agents, e.g. gliclazide, tolbutamide
- Ivabradine
- Methylphenidate
- Omeprazole
- Oral contraceptives
- Oxycodone
- SSRIs, e.g. paroxetine, trazodone, sertraline and other serotonergic agents, e.g. nefazodone, venlafaxine
- Statins, e.g. simvastatin
- Talinolol
- Theophylline
- Voriconazole
- Zolpidem

(Bone and Mills, 2013)

A.VOGEL NEUROFORCE FORMULA contains small quantities of *Vitex agnus-castus* L. (0,07 ml / 1 ml). *Vitex agnus-castus* L., in substantially larger doses, should be used with caution and/or under medical supervision when co-administering the following medicine:
- hormone replacement therapy
- oral contraceptives
- progestogens

No interactions are expected with the dosages recommended for A.VOGEL NEUROFORCE FORMULA.
(Bone & Mills, 2013)

Paediatric population
- A.VOGEL NEUROFORCE FORMULA, (due to its alcohol content) may impact sensitive individuals during daily activities such as learning ability, physical activities, or affect appetite or sleep patterns.

4.5 Interaction with other medicines and other forms of interaction
Refer to section 4.4.

4.6 Fertility, pregnancy and lactation
Women of childbearing potential/Contraception in males and females
No information available.
Interactions: refer to section 4.4.

Pregnancy
No information available.
No specific safety studies on the use of A.VOGEL NEUROFORCE FORMULA in pregnancy have been conducted. Although homeopathic remedies are generally considered to be suitable for use during pregnancy, A.VOGEL NEUROFORCE FORMULA contains very small quantities of *Vitex agnus-castus* which should be used with caution in pregnancy, please consult a doctor, pharmacist or healthcare provider for further advice.

Breastfeeding
No information available.
No specific safety studies on the use of A.VOGEL NEUROFORCE FORMULA in breastfeeding have been conducted. Although homeopathic remedies are generally considered to be suitable for use during breastfeeding, A.VOGEL NEUROFORCE FORMULA contains very small quantities of *Hypericum perforatum* which should be used with caution in breastfeeding, please consult a doctor, pharmacist or healthcare provider for further advice.

Fertility
Fertility studies have not been performed.
No effect on fertility expected.

4.7 Effects on ability to drive and use machines
A.VOGEL NEUROFORCE FORMULA, (due to its alcohol content) 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.

4.8 Undesirable effects
If symptoms of hypersensitivity occur e.g. rash, urticaria or angioedema of the skin, discontinue use of product, and contact a healthcare professional immediately.

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. Healthcare 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

4.9 Overdose
In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).
Treatment of overdose should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Homeopathy D33.2
Has traditionally been used according to homeopathic principles.

5.2 Pharmacokinetic properties
No information available.

5.3 Preclinical safety data
No information available.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Contains more than 50 % *v/v* alcohol.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store at or below 25 °C.
Protect from light.
Store in the original package/container.

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: 30 ml

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product
No special requirements.

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION
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8 REGISTRATION NUMBER(S)/REFERENCE NUMBER
U 930 (ACT 101/1965)

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

10 DATE OF REVISION OF TEXT
August 2021

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