PROFESSIONAL INFORMATION FOR

ECHINAFORCE® HOT DRINK

COMPLEMENTARY MEDICINE

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

SCHEDULING STATUS
S0

1 NAME OF THE MEDICINE

A.VOGEL ECHINAFORCE® HOT DRINK, syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL contains

Echinacea purpurea (L.) MOENCH (Purple coneflower) [Fresh aerial parts, 1:12 extract providing 95 mg dry plant equivalent]	1 140 mg
Echinacea purpurea (L.) MOENCH (Purple coneflower) [Fresh root, 1:11 extract providing 5,5 mg dry plant equivalent]	60 mg

Contains sugar as sucrose	4,121 g/5 mL
Ethanol	33 mg/5 mL (0,66 % *w/v*)
Preservative as potassium sorbate	7 mg/5 mL (0,14 % *w/v*)

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup
Dark red to dark violet viscous liquid with an aromatic, fruity, elder like odour and a fruity, sweet and light sour taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL ECHINAFORCE® HOT DRINK is a Western Herbal medicine for the treatment of cold and flu symptoms like coughs, mucus congestion, runny eyes, sore throats, headaches, muscle aches and fever.
By supporting the immune system, it also helps improve resistance to recurrent infections.

4.2 Posology and method of administration

Posology
For treatment, start the therapy at first signs of infection.

Adults and adolescents over 12 years
Day 1 to 3: 5 mL five times per day.
Day 4 to 10: 5 mL three times per day.

Children 6 - 12 years
Day 1 to 3: 5 mL three times per day.
Day 4 to 10: 5 mL two times per day.

Duration of use
A.VOGEL ECHINAFORCE® HOT DRINK is suitable for the acute treatment over 10 days. Generally, *Echinacea*-containing products should not be taken for more than 8 weeks continuously.

Paediatric population
A.VOGEL ECHINAFORCE® HOT DRINK is not indicated for children under 6 years of age.
The use in children under 1 year of age is contraindicated (see section 4.3).

Method of administration
For oral use only.
Shake before use.
The syrup should be made into a hot drink by diluting it in hot water.

4.3 Contraindications

- Hypersensitivity to *Echinacea*, to plants of the *Asteraceae* (*Compositae*) family or to any of the excipients listed in section 6.1.
- Because of their immunomodulatory activity, *Echinacea* extracts must not be used in cases of progressive systemic disorders, autoimmune diseases, immunosuppression, and diseases of the white blood cell system.
- Children under 1 year of age.

4.4 Special warnings and precautions for use

Persistent symptoms
If severe symptoms persist for more than 10 days or symptoms worsen or high fever occurs during the use of A.VOGEL ECHINAFORCE® HOT DRINK, a doctor, pharmacist or other health care provider should be consulted.

Atopic patients
There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using A.VOGEL ECHINAFORCE® HOT DRINK.

Excipients with known effect
Sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take A.VOGEL ECHINAFORCE® HOT DRINK.

Ethanol: A.VOGEL ECHINAFORCE® HOT DRINK contains 33 mg of alcohol (ethanol) in each 5 mL dose which is equivalent to 6,6 mg/mL. The amount in each dose (5 mL) of this medicine is equivalent to less than 1 mL beer or 1 mL wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

4.5 Interaction with other medicines and other forms of interaction

There is no evidence from limited interaction studies that *Echinacea* extracts will interact with other medicinal products.

4.6 Fertility, pregnancy and lactation

Pregnancy
Data on a limited number (several hundreds) of exposed pregnancies indicate no adverse effects of *Echinacea* extracts on pregnancy or on the health of the foetus/new-born child. Data concerning the immune system of the new-born child are not available. To date, no other relevant epidemiological data are available.

As a precautionary measure and in the absence of additional data, the use during pregnancy should be done under supervision of and on recommendation of a doctor.

Breastfeeding
As a precautionary measure and in the absence of additional data, the use during breastfeeding should be done under supervision of and on recommendation of a doctor.

Fertility
Fertility studies have not been performed (see section 5.3).

4.7 Effects on ability to drive and use machines

A.VOGEL ECHINAFORCE® HOT DRINK has no or negligible effect on mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects
Tabulated summary of adverse reactions

System Organ Class	Frequency	Adverse reactions
Immune system disorders	Frequency unknown	Hypersensitivity, e.g. rash, urticaria, itching, swelling of the face may occur (see sections 4.3 and 4.4). Severe hypersensitivity reactions, e.g. Stevens-Johnson Syndrome, angioedema of the skin, Quincke oedema, bronchospasm with airway obstruction, asthma and anaphylactic shock.

Paediatric population
Frequency, type, and severity of adverse reactions in children are expected to be the same as in adults.

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 requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
In addition, side-effects can also be reported to info@pharmacorp.co.za.

4.9 Overdose
None known.
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
Immunomodulators of plant origin / L03AW05
Other preparations for respiratory system / R07AX

Mechanism of action
Symptoms associated with cold and flu episodes are primarily caused by inflammatory mediators (cytokines) produced by the epithelium and the immune system when encountering an infectious particle.

In vitro ECHINAFORCE® potently regulates the expression of cytokines like TNF-α, IL-6 and IL-8, and acts as an immune-modulator: Excessive production of inflammatory cytokines and chemokines are dampened. Alkylamides in ECHINAFORCE® were shown to be key players in the process of immune modulation via acting on CB-2 receptors on immune cells. Interaction with CB-2 receptor was confirmed by computer modelling techniques.

ECHINAFORCE® exhibits potent antiviral effects, inhibits viral replication and pathogenicity (the ability of an organism to infect a host) of Influenza-, Respiratory Syncytial-, Parainfluenza- and at higher concentrations also of Rhinoviruses. Modulation of inflammatory cytokines was further demonstrated after infection of airway cell lines (A549 or MDCK-1) and organotypic 3D tissue cultures.

ECHINAFORCE® induced phagocytotic capacity in human granulocytes by 56 % when comparing to control.

Anti-oxidative effects were attributed to ECHINAFORCE®: Cyclooxygenase and Lipoxygenase enzymes were inhibited by 44,7 ±15,3 % and 93 ±7 %, respectively.

Direct and indirect antiviral activity by secretion of interferon was demonstrated for *Echinacea purpurea*.

The efficacy of ECHINAFORCE® has been accessed in an *ex vivo* study. Leukocytes isolated from ECHINAFORCE®-treated volunteers showed modulated activity. Expression of cytokines (e.g. TNF-α) was inhibited under *ex vivo* stimulation with LPS.

These results were confirmed in a clinical study with 30 subjects treated for 8 days with ECHINAFORCE®. Daily blood samples were *ex vivo* stimulated with SEB/LPS and a panel of cytokines was measured. During treatment with ECHINAFORCE® TNF-α and IL-1 were reduced and IL-10 increased under concomitant induction of chemokines (MCP-1 and IL-8).

5.2 Pharmacokinetic properties
Pharmacokinetic studies on ECHINAFORCE® were performed over 4 hours in volunteers after ingesting oral drops (tincture mixture) or tablets (250 mg total weight) both corresponding to a typical daily dose (4 mL / 12 tablets containing 400 mg ECHINAFORCE® tincture mixture each). For the oral drops a peak serum-level of 0,40 ng/mL dodeca-2E,4E,8Z,10E/Z-tetraenoic acid isobutylamide was detected after 30 minutes. For the tablets after 45 min 0,12 ng/mL of the compound was measured. A total amount of bioavailable dodeca-2E,4E,8Z,10E/Z-tetraenoic acid isobutylamide was expressed as area-under-curve for ECHINAFORCE® oral drops (27,55 ± 8,94 ng x min/mL) and for the ECHINAFORCE® tablets (11,36 ± 2,74 ng x min/mL).

Additional pharmacokinetic studies were performed with other ECHINAFORCE® products (tablets and sore-throat spray). Isobutylamides (alkylamides) were resorbed from all formulations and bioavailability was comparable between the different ECHINAFORCE® products. The data show that pharmacologically active constituents in ECHINAFORCE® principally are bioavailable, while exhibiting a fast resorption.

5.3 Preclinical safety data
Echinacea purpurea showed no toxicity in single dose toxicity (rodents), repeated-dose toxicity (rodents) and genotoxicity/carcinogenicity studies.

No mutagenic effects of ECHINAFORCE® were detected in Ames' test (with or without metabolic activation).

Non-clinical studies on reproductive toxicity have not been performed.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Citric acid monohydrate
Elderberry juice, concentrated
Modified starch
Potassium sorbate
Sucrose
Triglycerides, medium chain
Water, purified

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
30 months unopened.
After opening use within 1 month.

6.4 Special precautions for storage
Unopened, store below 25 °C.
After opening, store in the refrigerator (below 8 °C).
Store in the original container.

6.5 Nature and contents of container
Amber glass bottle with white pilfer-proof screw cap.

Pack size: 100 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
To be allocated.

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

10 DATE OF REVISION OF TEXT
November 2024