

PROFESSIONAL INFORMATION FOR A.VOGEL ECHINA-MED FORTE

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 ECHINA-MED FORTE, tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains

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

Contains sugar

- Sucrose 0,9 mg per tablet

Contains sugar as sugar-alcohols

- Mannitol 272,9 mg per tablet
- Sorbitol 135,0 mg per tablet

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

Homogeneous, round, biconvex, bevelled, off-white to slightly green tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

A.VOGEL ECHINA-MED FORTE is a high potency herbal medicine for the treatment of colds and relief of cold and flu symptoms such as nasal complaints, sore throat, cough, headache, myalgia, and fever. It shortens the duration of upper respiratory tract infections and improves immune resistance to colds and flu.

4.2 Posology and method of administration

Posology

Adults and adolescents over 12 years

Treatment:

Day 1 to 3: One (1) tablet five times per day.

Day 4 to 10: One (1) tablet three times per day.

Immune support maintenance:

One (1) tablet two times per day.

Children 6 – 12 years

Treatment:

Day 1 to 3: One (1) tablet three times per day.

Day 4 to 10: One (1) tablet two times per day.

Immune support maintenance:

One (1) tablet per day.

Treatment: Start therapy at the first signs/symptoms of infection.

Immune support maintenance: During times of increased infection risk. May be used continuously for 4 months.

Paediatric population

A.VOGEL ECHINA-MED FORTE 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.

The tablets to be taken with water before meals or melt in the mouth.

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 symptoms persist for more than 10 days, or symptoms worsen, or high fever occurs during the use of A.VOGEL ECHINA-MED FORTE, 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 ECHINA-MED FORTE.

Excipients with known effect

Sorbitol: Patients with hereditary fructose intolerance (HFI) should not take A.VOGEL ECHINA-MED FORTE.

Sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take A.VOGEL ECHINA-MED FORTE.

4.5 Interactions 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 ECHINA-MED FORTE 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 drug 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

Note: A.VOGEL ECHINA-MED and A.VOGEL ECHINAFORCE® product range
The active ingredient is an extract derived from fresh aerial parts and roots in a 95:5 ratio of *Echinacea purpurea* (purple coneflower), termed ECHINAFORCE® extract. The 95:5 active ingredient ratio is the same in all products within the A.VOGEL ECHINA-MED/ECHINAFORCE® range.
Refer to each product's package insert for more information.

Mechanism of action

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

In vitro ECHINAFORCE® potentially regulates the expression of cytokines like TNF- α 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 $44,7 \pm 15,3$ % and 93 ± 7 %, respectively.

Direct and indirect antiviral activity by secretion of interferon was demonstrated for *Echinacea purpurea*. *Echinacea* extract inhibited the receptor binding activity of viruses, suggesting that the extract interfered with the viral entry into cells.

The efficacy of ECHINAFORCE® has been assessed in an *ex vivo* study. Leukocytes isolated from ECHINAFORCE®-treated volunteers showed modulated activity. Expression of cytokines (e.g. IL-8 and 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 with the same active substances in identical ratio as in ECHINA-MED FORTE) or tablets (400 mg total extract per tablet) both corresponding to a typical daily dose (4 mL / 12 tablets). 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 ($27,55 \pm 8,94$ ng x min/mL) and for the ECHINAFORCE® tablets ($11,36 \pm 2,74$ 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® are bioavailable, while exhibiting a fast absorption.

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® extract 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

Croscarmellose sodium (E468)
Magnesium stearate (E470b)
Mannitol (E421)
Medium-chain triglycerides
Sorbitol (E420)
Sucrose laurate (E473)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Amber glass bottles: 36 months.
Blister strips: 24 months.

6.4 Special precautions for storage

Store at or below 25 °C, in a dry place.
Store in the original package.

6.5 Nature and contents of container

Packaging

Blister strips containing 10 tablets per blister.
Amber glass bottles with a tamper evident seal and closed with a cap.
Blister strips and glass bottles are packed in an outer carton.

Pack sizes

30 or 60 tablets.
Not all pack sizes may be marketed.

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 THE TEXT

April 2026