Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Echinaforce Sore Throat Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 spray dose contains:
- 379.9 mg of tincture from fresh *Echinacea purpurea* (L.) Moench, herba (Purple coneflower herb) (1:12-13). Extraction solvent: ethanol 65% V/V
- 20.0 mg of tincture from fresh *Echinacea purpurea* (L.) Moench, radix (Purple coneflower root) (1: 11-12). Extraction solvent: ethanol 65% V/V
- 189.2 mg of tincture from fresh *Salvia officinalis* L., folium (Sage leaves) (1:17-18). Extraction solvent: ethanol 68% V/V

1 spray is approximately equal to 0.22 ml

Excipients with known effect:
Each 2 spray dose contains 129 mg sorbitol, 163 mg ethanol, 8.8 mg soy lecithin and 1.4 mg sucrose.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray, solution (Oromucosal spray)
Brown to yellow-green, clear liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used to relieve sore throats associated with coughs, colds and flu-like illnesses, exclusively based on long-standing use.

This product is indicated for use in adults and older people over 18 years

4.2 Posology and method of administration

Posology

Adults, and older people over 18 years:
2 sprays six to ten times daily.

The use in children and adolescents under 18 years of age is not recommended (see section 4.4 Special warnings and precautions for use).

Method of administration

Fit the nozzle onto the top of bottle.

Before using the product for the first time activate the spray by pressing the pump 2-3 times.

To use the spray, shake the bottle well, place the nozzle just inside the mouth and point it towards the back of the throat. Press the pump to spray.

For oral short-term use only.

Duration of use

Do not use the product for more than 7 days. If symptoms worsen during the use of the product or persist for more than 7 days, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

4.3 Contraindications

Hypersensitivity to the active substances, plants of the Asteraceae (Compositae) family or to any of the excipients listed in section 6.1.

This product contains soy lecithin. Patients with known allergy to peanut or soya should not take this medicinal product.

Because of their immuno-modulatory activity, Echinacea extracts must not be used in cases of progressive systemic disorders (tuberculosis, sarcoidosis), autoimmune diseases (e.g. collagenoses, multiple sclerosis), immunodeficiences (e.g. HIV infections, AIDS), immunosuppression (e.g. oncological cytostatic therapy, history of organ or bone marrow transplant) and diseases of the white blood cell system (e.g. agranulocytosis, leukaemias).

Refer to Section 2, Qualitative and Quantitative Composition for soy lecithin content.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

The use in adolescents and children below 18 years of age is not recommended because a safe use has not been sufficiently documented.

Do not use and consult your doctor if you have difficulty swallowing or breathing, if sore throat is severe and is accompanied by high fever, headache, nausea or vomiting.

Avoid contact with eyes.

If the symptoms worsen during the use of the product, or if symptoms persist for more than 7 days, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using Echinacea.

This medicine contains 163 mg of alcohol (ethanol) in each dose (2 sprays). The amount in each dose (2 sprays) of this medicine is equivalent to less than 5 ml beer or 2 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 129 mg of sorbitol in each dose (2 sprays). Sorbitol is a source of fructose. Patients with hereditary fructose intolerance (HFI) should not take this medicinal product. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Refer to Section 2, Qualitative and Quantitative Composition for sorbitol, ethanol, and sucrose content.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed with this product. This product should not be used concomitantly with immunosuppressant medications. The intake of Sage folium preparations might influence the effect of medicinal products acting via the GABA receptor (e.g. barbiturates, benzodiazepines), even if not seen clinically. Therefore the concomitant use

with such medicinal products is not recommended. Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole).

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of Echinaforce Sore Throat Spray in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Echinaforce Sore Throat Spray is not recommended during pregnancy.

There is insufficient information on the excretion of Echinaforce Sore Throat Spray/metabolites in human milk. A risk to newborn/infants cannot be excluded. Echinaforce Sore Throat Spray should not be used during breast-feeding.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

This product contains alcohol (see Section 4.4 for details of alcohol content).

4.8 Undesirable effects

Common (≥1/100 to <1/10)
Rash on the buccal mucosa and a burning sensation of the throat have been reported in a clinical trial with this product.

Frequency not known
Hypersensitivity reactions (rash, urticaria, Stevens-Johnson Syndrome, angioedema of the skin, bronchospasm with obstruction, asthma and anaphylactic shock) may occur.

Echinacea can trigger allergic reactions in atopic patients. Association with autoimmune diseases (multiple sclerosis, erythema nodosum, immunothrombocytopenia, Evans Syndrome, Sjögren syndrome with renal tubular dysfunction) has been reported.

Leucopaenia may occur in long-term use (more than 8 weeks).

The alkylamides present in Echinaforce Sore Throat Spray can affect the buccal mucosa which may be experienced as tingling, irritation and numbness in the mouth, this is however considered to be part of the clinical effect.

If other adverse reactions not mentioned above occur, a doctor or pharmacist should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

Overdose of this product may result in alcohol intoxication: the amount of alcohol in a full bottle (11 g in 30 ml; equivalent to a small glass of wine) may result in intoxication and should be treated accordingly.

For Sage leaves overdose has been reported with a sense of heat, tachycardia, vertigo and epileptiform convulsions (seizures) after intake corresponding to more than 15 g sage leaves (equivalent to between 38 and 66 doses).

No case of overdose has been reported for Echinacea.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

The Echinaforce extract contained in Echinaforce Sore Throat Spray has been shown to be non-mutagenic in *Salmonella typhimurium* reverse mutation assay up to a dose of 5000 mcg/plate.

The Sage extract contained in Echinaforce Sore Throat Spray has also been shown to be non-mutagenic in *Salmonella typhimurium* reverse mutation assay up to a dose of 5000 mcg/plate.

Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed with Echinaforce Sore Throat Spray.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose laurate (E473)
Soy lecithin
Ethanol
Peppermint oil
Sorbitol, liquid (non crystallising)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened:
30 months

After first opening the container:
2 months

6.4 Special precautions for storage

This product does not require any special storage conditions.

6.5 Nature and contents of container

Brown glass flasks of hydrolytic glass Type III (Ph.Eur.) with air pump (snap-on-cap with spray pump; polyethylene / polyoxymethylene / stainless steel) and adapter (spray nozzle and actuator; polyethylene / polypropylene).
Pack size: 30 ml

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

A.Vogel Ireland Limited
Unit 3d
Killeen Road
Dublin 10
D10 TY20
Ireland

8 REGISTRATION NUMBER(S)

TR2309/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first registration: 24th April 2015
Date of last renewal: 23rd April 2020

10 DATE OF REVISION OF THE TEXT

October 2022