SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Echinaflu Effervescent Tablets
Echinacold Echinacea Cold & Flu Relief Effervescent Tablets
Boots Echinacea Cold & Flu Relief Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One effervescent tablet contains 176 mg of dried pressed juice from fresh flowering *Echinacea purpurea* (L.) Moench herb (20-28:1) (equivalent to 3520 mg – 4928 mg of fresh flowering *Echinacea purpurea* (L.) Moench herb).

One effervescent tablet contains 17.05 mmol (or 392 mg) sodium.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet

Round, flat, ivory-coloured effervescent tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used to relieve the symptoms of the common cold and influenza type infections based on traditional use only.

4.2 Posology and method of administration

For oral use only.

Adults, elderly and children over 12 years: the recommended dosage is 1 or 2 effervescent tablets daily, dissolved in a glass of water (about 200 ml). The dissolved tablets should be drunk immediately.

Not recommended for use in children under 12 years of age (see Section 4.4 Special warnings and precautions for use).

Start at first signs of common cold. Do not use the product for more than 10 days.

If symptoms worsen, or persist for more than 10 days, a doctor or a qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family.

Because of its immunostimulating activity, Echinacea must not be used in cases of progressive systemic disorders (tuberculosis, sarcoidosis), autoimmune diseases (e.g.: collagenoses, multiple sclerosis), immunodeficiencies (e.g.: HIV infection; AIDS), immunosuppression (e.g.: oncological cytostatic therapy; history of organ or bone marrow transplant), diseases of the white blood cell system (e.g.: agranulocytosis, leukemias) and allergic diathesis (e.g.: urticaria, atopic dermatitis, asthma).

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If the condition worsens, or high fever occurs during the use of the product, or if symptoms persist for more than 10 days, a doctor or qualified healthcare practitioner should be consulted.

The use in children under 12 years is not recommended because data are not sufficient and medical advice should be sought

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

In patients for whom sodium intake is of medical concern (e.g. patients with congestive heart failure, renal failure, nephrotic syndrome), the sodium content of this product should be taken into account. Refer to Section 2, Qualitative and Quantitative Composition for sodium chloride content.

4.5 Interaction with other medicinal products and other forms of interaction

Not to be used concomitantly with immunosuppressant medications such as ciclosporin and methotrexate.

4.6 Fertility, pregnancy and lactation

In the absence of sufficient data the use in pregnancy and lactation is not recommended.

Limited data (several hundreds of exposed pregnancies) indicate no adverse effects of Echinacea on pregnancy or on the health of the foetus/newborn child. Data concerning the immune system of the newborn child are not available. To date, no other relevant epidemiological data are available. The potential risk for humans is unknown.

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.

4.8 Undesirable effects

Hypersensitivity reactions (rash, urticaria, swelling of the face) may occur. Cases of severe hypersensitivity reactions such as Stevens-Johnson Syndrome, angioedema of the skin, Quincke oedema, bronchospasm with airway obstruction, asthma and anaphylactic shock) have been reported.

Echinacea can trigger allergic reactions in atopic patients.

Association with autoimmune diseases (encephalitis disseminata, erythema nodosum, immunothrombocytopenia, Evans Syndrome, Sjögren syndrome with renal tubular dysfunction) cannot be excluded.

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

The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.

4.9 Overdose

No case of overdose has been reported.

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

Reverse mutation assays (Ames test) on bacteria indicated that the product was not mutagenic in *Salmonella typhimurium* (strains TA 98, TA 100, TA 102, TA 1535 and TA 1537) mutation assays with or without metabolic activation.

Echinacea purpurea herba expressed juice showed no toxicity in single-dose toxicity (rodents), repeated-dose toxicity (4 weeks rodents) and *in vitro* and *in vivo* genotoxicity studies.

Tests on reproductive toxicity and on carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients of the herbal preparation:
Maltodextrin
Precipitated silicon dioxide
Citric acid monohydrate
Excipients of the tablet:
Ascorbic acid
Sodium hydrogen carbonate
Saccharin sodium
Sodium cyclamate
Citric acid anhydrous
Citric flavour Permaseal 84260-51.

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened
3 years.
After first opening the container
7 months.

6.4 Special precautions for storage

Store in the original packaging.
There are no special storage requirements

6.5 Nature and contents of container

Effervescent tablets are packed in polypropylene tubes with polyethylene closures filled with the drying agent silica gel.
One tube contains 20 effervescent tablets.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Schwabe Pharma (UK) Ltd
Alexander House, Mere Park,
Dedmere Road, Marlow, Bucks SL7 1FX

8 MARKETING AUTHORISATION NUMBER(S)

THR 23056/0041

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/01/2020

10 DATE OF REVISION OF THE TEXT

16/08/2022