1 NAME OF THE MEDICINAL PRODUCT

HRI Coldcare tablets Echinacea with Vitamin C and Zinc

H&B Echinacea with Vitamin C and Zinc tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains 56 mg of extract (as dry extract) from *Echinacea purpurea* root (equivalent to 338 mg- 450 mg of *Echinacea purpurea* (L.) Moench, root).

Extract Solvent Ethanol 75% w/w

Ancillary vitamins/minerals

Zinc	3.3 mg
(as Zinc Gluconate)	
Vitamin C	29.3 mg
(as Ascorbic Acid)	

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet.

Pale orange round deep biconvex, 9 mm in diameter.

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 administration

Adults, elderly and children over 12 years: the recommended dosage is 2 tablets twice a day.

This product is 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 medicinal product for more than 10 days. If symptoms worsen during the use of the product, 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, consult a doctor or qualified healthcare practitioner.

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

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

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.

No studies on the effects on fertility have 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, Stevens-Johnson Syndrome, angioedema of the skin, Quincke edema, bronchospasm with obstruction, asthma and anaphylactic shock) may occur.

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) has been reported.

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 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: Yellow card sceheme Website: 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

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core

(Extract Excipients)

Maltodextrin

Colloidal anhydrous silica

Calcium hydrogen phosphate dihydrate

Microcrystalline Cellulose

Croscarmellose Sodium

Colloidal Hydrated Silica

Magnesium Stearate

Stearic Acid

Tablet Coating

Hypromellose

Red Iron Oxide (E172)

Yellow Iron Oxide (E172)

Titanium Dioxide (E171)

Purified Talc

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 25 °C. Store in the original packaging

6.5 Nature and contents of container

Tablets are packed into PVC aluminium foil blister strips of 15 tablets.

Pack sizes: 30, 45, 60, 90 film coated tablets

Not all pack Sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

The Herbal Research Company Limited

(Trading as Jessup Marketing)

27 Old Gloucester Street

London

WC1N 3XX

8 MARKETING AUTHORISATION NUMBER(S)

THR 02231/0011

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/02/2018

10 DATE OF REVISION OF THE TEXT

03/02/2022