SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Galpharm Herbal Cold and Flu Sachets

Sainsbury's Herbal Cold and Flu Sachets

Asda Herbal Cold and Flu Sachets

Tesco Herbal Cold and Flu Sachets

Morrisons Herbal Cold and Flu Sachets

Superdrug Herbal Cold and Flu Sachets

Wilko Herbal Cold and Flu Sachets

Boots Herbal Flu Relief Sachets

Herbalstore Herbal Cold and Flu Sachets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

71.5 mg extract (dry extract) from *Echinacea purpurea* root (6-7:1)

(equivalent to 429 – 500 mg of *Echinacea purpurea* (L.) Moench, root)

Extraction solvent: Ethanol 30% v/v

Ancilliary vitamins / minerals

Zinc	5 mg
(as 13.73 mg sulphate monohydrate)	
Ascorbic Acid	60 mg

Excipients:

Each sachet contains 45 mg aspartame and 104 mg sodium.

For full list of excipients, see 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution.

Off white powder.

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

Adults, the elderly and children over 12 years: 1 sachet 3 times a day.

For oral administration after dissolution in water. Pour the contents of one sachet into a mug. Fill it with hot, not boiling, water and stir until dissolved and drink.

Start at first sign of common cold or influenza type infection. 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 physician or a qualified healthcare practitioner should be consulted.

Not recommended for children under 12 years of age (see section 4.4 ‘Special warnings and precautions for use’.

4.3 Contraindications

Hypersensitivity to Echinacea, zinc or ascorbic acid or to the 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).

Children under 12 years of age.

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.

This formulation is not suitable for children under 12 years.

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

Contains aspartame (E951) a source of phenylalanine. May be harmful for people with phenylketonuria. See section 2.

Contains sodium. To be taken into consideration by patients on a controlled sodium diet. See section 2.

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 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.

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 qualified healthcare practitioner should be consulted.

4.9 Overdose

Symptomatic and supportive measures should be taken as appropriate.

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 on carcinogenicity have not been performed with *Echinacea purpurea* root.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients of the herbal preparation;

Maltodextrin

Silica, colloidal anhydrous

Other excipients;

Maltodextrin
Sodium Citrate
Citric Acid
Acesulflame K
Aspartame (E951)
Quinoline Yellow (E104)
Lemon Flavour F/29088
Lemon Flavour F/29089
Lemon Flavour F/28151
Lemon Flavour 501.476/AP05.04

6.2 Incompatibilities

None applicable.

6.3 Shelf life

Shelf life of product as packaged for sale

36 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Paper/foil laminate sachets consisting of:

Bleached MG paper outer – 40 g/m^2

LD Polyethylene – 12 g/m^2

Aluminium foil 12 – 15 microns

Surlyn 25 g/m^2

Five or ten sachets are contained in a boxboard carton.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Wrafton Laboratories Limited

Braunton

Devon

EX33 2DL

8 MARKETING AUTHORISATION NUMBER(S)

THR 12063/0010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/03/2010

10 DATE OF REVISION OF THE TEXT

23/03/2010