Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Holland & Barrett Echinacea Cold and Flu Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 140mg of extract (as dry extract) from *Echinacea purpurea* root (equivalent to 838 mg –1117 mg of *Echinacea purpurea* (L.) Moench (purple coneflower), root).

Extraction solvent: Ethanol 75% v/v.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard Capsule (Capsules)

Two piece clear hard capsules with grey/brown fill.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product used to relieve common cold and flu-like symptoms in adults and adolescents over 12 years, exclusively based upon long-standing use.

4.2 Posology and method of administration

For oral short-term use only.

Adults, older people and adolescents over 12 years:
Take one capsule 2 times daily. Swallow the whole capsule with water. Start at the first sign of a common cold.

Do not exceed the stated dose.

Duration of use:
Do not use this product for more than 10 days.

The use in children below 12 years of age is not recommended (see 4.4 Special warnings and precautions for use).

If symptoms worsen or persist for more than 10 days, or if new symptoms develop, or if high fever occurs whilst taking this product, a doctor or pharmacist should be consulted.

4.3 Contraindications

Do not use in cases of known hypersensitivity to *Echinacea purpurea* root, to plants of the Asteraceae (Compositae) family or to any of the excipients listed in section 6.1.

Because of their immune-modulatory activity, Echinacea extracts must not be used in cases of progressive systemic disorders (Tuberculosis sarcoidosis), autoimmune diseases (e.g. collagenosis, multiple sclerosis), immunodeficiencies (e.g. HIV infection, 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).

4.4 Special warnings and precautions for use

Do not exceed the stated dose

The use in children below 12 years of age is not recommended because a safe use has not been sufficiently documented.

If symptoms worsen or high fever occurs during the use of this medicinal product or if symptoms persist for more than 10 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 a qualified healthcare professional e.g. a doctor or pharmacist before using Echinacea.

4.5 Interaction with other medicinal products and other forms of interactions

This product should not be used concomitantly with immunosuppressant medications.

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of *Echinacea purpurea* root in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Holland and Barrett Echinacea Cold and Flu Hard Capsules is not recommended during pregnancy and in women of child-bearing potential not using contraception.

There is insufficient information on the excretion of *Echinacea purpurea* (L.)/metabolites in human milk. A risk to newborns/infants cannot be excluded. Holland & Barrett Echinacea Cold and Flu Hard Capsules should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

● Echinacea can trigger allergic reactions in atopic patients.
● Hypersensitivity reactions of the following nature may occur
- Anaphylactic shock
- Bronchospasm with obstruction
- Asthma
- Urticarial rash
- Angioedema of the skin
- Steven-Johnson Syndrome
● Association with autoimmune diseases (multiple sclerosis, erythema nodosum, immune thrombocytopaenia, Evans Syndrome, Sjogren's syndrome with renal tubular disfunction) has been reported.
● Leucopaenia may occur in long-term use (more than 8 weeks)

The frequency of the listed side effects is not known (cannot be estimated from the available data).

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

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

In vitro tests for detection of gene mutation (Ames test) with Echinacea purpurea root did not demonstrate genotoxic activity. Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Magnesium stearate
Silica colloidal hydrated

Excipients in the extract:
Maltodextrin
Silica colloidal anhydrous

Capsule Shell:
Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25ºC.
Keep the bottle tightly closed in order to protect from light and moisture.

6.5 Nature and contents of container

Container:
Green polyethylene terephthalate (PET) bottles with a polypropylene cap and an inner seal liner made up of polyester, polymer adhesive layer, polyolefin foam and aluminium foil.

Pack size: 30 capsules, 60 capsules or 100 capsules
Not all pack sizes maybe marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Holland & Barrett Limited
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8 REGISTRATION NUMBER(S)

TR23157/007/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 17th January 2014
Date of last renewal: 16th January 2019

10 DATE OF REVISION OF THE TEXT

February 2021