Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Irish Botanica Echinacea Oral Liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2.5 ml of oral liquid contains 2.5 ml of tincture from dried *Echinacea purpurea* (L.) Moench, radix (Purple Coneflower, root) (1:3). Extraction solvent: Ethanol 45 % v/v.

Excipient with known effect:
One dose (2.5 ml) of oral liquid also contains approximately 0.9 g of ethanol (alcohol).

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral Liquid.

Medium to dark, clear brown liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Irish Botanica Echinacea Oral Liquid is a traditional herbal medicinal product used in adults to relieve common cold and flu-like symptoms, exclusively based on long-standing use.

4.2 Posology and method of administration

For oral short-term use only.

Adults and older people:

Take one 2.5ml spoonful, in water, three times a day.

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

Treatment should start at the first signs of common cold.

If symptoms persist, worsen or do not improve after 10 days use of Irish Botanica Echinacea Oral Liquid, a doctor or pharmacist should be consulted.

4.3 Contraindications

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

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), and diseases of the white blood cell system (e.g. agranulocytosis, leukemias).

4.4 Special warnings and precautions for use

Do not exceed the stated dose.
If symptoms worsen, persist for more than 10 days or high fever occurs during the use of this medicinal product, a doctor or pharmacist should be consulted.
The use in children below 18 years of age is not recommended because a safe use has not been sufficiently documented.
There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using Echinacea.
This medicine contains 900mg of alcohol (ethanol) in each 2.5 ml dose, which is equivalent to 23 ml beer or 9 ml wine per 2.5 ml dose. The amount of alcohol in this medicine is not likely to have an effect in adults.

4.5 Interaction with other medicinal products and other forms of interaction

Contains alcohol, and should therefore be avoided in patients taking other medications known to interact with alcohol (e.g. metronidazole).

Not to 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). Irish Botanica Echinacea Oral Liquid is not recommended during pregnancy and in women of childbearing potential not using contraception.

There is insufficient information on the excretion of Echinacea purpurea root/metabolites in human milk. A risk to newborns/infants cannot be excluded. Irish Botanica Echinacea Oral Liquid should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

No studies on the effect of this product on the ability to drive or use machinery have been performed.

This product contains alcohol (see section 4.4 for details of alcohol content). Overdose of this product may result in alcohol intoxication.

4.8 Undesirable effects

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. The frequency of the listed side effects is not known.

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, Website: www.hpra.ie

4.9 Overdose

No case of overdose has been reported.
Overdose of this product may result in alcohol intoxication. One 200ml bottle of this product contains 71 g ethanol. This is equivalent to 4.5 large glasses of wine and may result in intoxication which should be treated accordingly.

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

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

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 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

Amber glass bottle with a HDPE/PP/PE tamper-evident, child-resistant screw cap with a polyethylene liner.

Pack sizes:100 ml and 200 ml.
Not all pack sizes may be marketed.

The product is supplied with a CE marked polyethylene measuring cup capable of measuring 2.5 ml.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

3 - 5 Charvey Business Park Rathnew Co. Wicklow Ireland

7 REGISTRATION HOLDER

Irish Botanica
3-5 Charvey Business Park
Rathnew
Co. Wicklow
Ireland

8 REGISTRATION NUMBER(S)

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 26th of May 2017
Date of last renewal: 25th of May 2022

10 DATE OF REVISION OF THE TEXT

May 2023