Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Natures Aid Echineeze Echinacea tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 62.3mg of extract (as dry extract) from *Echinacea purpurea* (L.) Moench, radix (equivalent to 373.8mg – 436.1mg of purple coneflower root). Extraction solvent: Ethanol 30% v/v.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Beige circular convex uncoated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

For oral administration.
For oral short-term use only.
Adults, elderly and children over 12 years: take one tablet three times a day.
The use in children below 12 years of age is not recommended (see 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 qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

4.3 Contraindications

Do not use in cases of known hypersensitivity to Echinacea, to plants of the Asteraceae (Compositae) family or to any of the excipients. 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) 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 this product, or if symptoms persist for more than 10 days, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.
The use in children below 12 years of age is not recommended because a safe use has not been sufficiently documented.
Keep out of the sight and reach of children
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

Pregnancy and lactation
In the absence of sufficient data EchinEeze Echinacea Tablets is not recommended for use in pregnancy and in women of child-bearing potential not using contraception.
Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).
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.
There is insufficient information on the excretion of Echinacea purpurea (L.)/metabolites in human milk. A risk to newborns/infants cannot be excluded. EchinEeze Echinacea Tablets should not be used during breast-feeding.

Fertility
No studies with Echinacea purpurea (L) in humans have been conducted to evaluate the effects on fertility.

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 qualified healthcare professional 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 national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

No relevant pharmacodynamic data are available.

5.2 Pharmacokinetic properties

No relevant pharmacokinetic data are available

5.3 Preclinical safety data

In a standard Ames test mutagenic activity was observed in salmonella strain (TA102). This was not evident when the test was repeated in a non-GLP assay. It is accepted that the totality of the data indicate Echinacea purpurea(L.) Moench root is not mutagenic. Tests on reproductive toxicity and on carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Herbal extract:
Maltodextrin
Silica, colloidal hydrated.

Tablet core:
Calcium hydrogen phosphate dihydrate
Cellulose, microcrystalline
Silica, colloidal hydrated.
Croscarmellose sodium
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Ph Eur type III glass bottles with polypropylene closure incorporating an induction heat seal liner. Printed card outer carton containing Patient Information Leaflet.
Pack sizes of 30, 60, 90, 120, and 180 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Clonmel Healthcare Ltd
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Clonmel
Co. Tipperary
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8 REGISTRATION NUMBER(S)

TR0126/311/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th October 2022

10 DATE OF REVISION OF THE TEXT