6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose (capsule shell)

6.2 Incompatibilities

Not Applicable.

6.3 Shelf-life

2 years.

6.4 Special Precautions for storage

Store below 25°C
Store in the original package.

6.5 Nature and contents of container

Duma 110ml HDPE plastic container and tamper evident threaded Duma cap.

Duma 200ml HDPE plastic container and tamper evident Duma cap.

EKINALIFE pack contains 60 or 120 Capsules.

6.6 Special precautions for disposal

There are no special precautions for disposal.

7 MARKETING AUTHORISATION HOLDER

Bio-Health Limited
Culpeper Close
Medway City Estate
Rochester
Kent
ME2 4HU

8 MARKETING AUTHORISATION NUMBER(S)

THR 15817/0008

9 DATE OF REGISTRATION

13/07/2011

10 DATE OF REVISION

13/07/2011

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BIO-HEALTH®

Ekinalife®

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

Ekinalife
Summary of Product Characteristics

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1 NAME OF THE MEDICINAL PRODUCT

EKINALIFE

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains:

200mg of *Echinacea pallida* root (*Echinacea pallida.* Nutt.) and

200mg of *Echinacea purpurea* root (*Echinacea purpurea* (L.) Moench.)

For list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsules.
Clear size 0 hard capsules.

The capsules are hard, clear, oblong and contain a dark brown powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

EKINALIFE is 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 use only.

Start at the first signs of the common cold.

Adults, elderly and children over 12 years. Take one capsule 2 times a day, morning and night, swallowed with water.

Maximum daily dose:- 2 capsules.

Duration of use:-
Do not use this product for more than 10 days.
If symptoms persist, worsen or do not improve after 10 days use of EKINALIFE, a doctor or a qualified healthcare practitioner should be consulted.

Not recommended for use by children under 12 years of age (see Section 4.4. Special Warnings and Precautions for Use).

4.3 Contra-indications

Hypersensitivity to Echinacea or to plants of the Asteraceae (Compositae) family or to any of the excipients.

Because of Echinacea's immunostimulating activity, EKINALIFE must not be used in cases of progressive systemic diseases such as:- tuberculosis, sarcoidosis, autoimmune diseases (e.g. collagenoses, multiple sclerosis), immunodeficiencies (e.g. HIV infection, AIDS), immunosuppression (e.g. oncological cytostaic therapy, history of organ or bone marrow transplant) diseases of the white blood cell system (e.g. agranulocytosis, leukaemias) and allergic diathesis (e.g. urticaria, atopic dermatitis, asthma).

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4.4 Special Warnings and Precautions for Use

Do not exceed the stated dose.

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

If the symptoms worsen or high fever occurs during the use of EKINALIFE, or if symptoms persist for more than 10 days, a doctor or qualified healthcare practitioner should be consulted. There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before taking EKINALIFE.

4.5 Interaction with other medicaments and other forms of interaction

EKINALIFE should not be taken concomitantly with immunosuppressant medications such as ciclosporin or methotrexate.

4.6 Pregnancy and Lactation

The safety of EKINALIFE during pregnancy and lactation has not been established.
Due to the lack of sufficient data, use during 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 to 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, angiodema of the skin, Quincke oedema, bronchospasm with obstruction, asthma, and anaphylactic shock) may occur. Echinacea can trigger allergic reactions in atopic patients. Association with autoimmune diseases (encephalitis disseminate, erythema nodosum, immunothrombocytopenia, Evans syndrome, Sjogren syndrome with renal tubular dysfunction) has been reported. Leucopenia may occur in long-term used (more than 8 weeks).

The frequency is not known. If other adverse reactions not mentioned occur, a doctor or a qualified healthcare practitioner should be consulted.

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

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

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