Potter’s Skin Clear Tablets

THR 33656/0049

UKPAR

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POTTER’S SKIN CLEAR TABLETS

THR 33656/0049

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Vifor Pharma UK Ltd (trading as Potters) a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Potter’s Skin Clear Tablets (Traditional Herbal Registration number: THR 33656/0049) on 21 January 2013. Potter’s Skin Clear Tablets is available without prescription and can be bought from pharmacies and other outlets.

Potter’s Skin Clear Tablets is a traditional herbal medicinal product used for the symptomatic relief of minor skin conditions such as spots, pimples and blemishes, based on traditional use only.

This registration is based exclusively upon evidence of the use of *Echinacea angustifolia* root as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
# Scientific Discussion

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Potter’s Skin Clear Tablets (THR 33656/0049) to Vifor Pharma UK Ltd on 21 January 2013. This product is on the general sales list (GSL).

A product licence of right (PLR) was originally granted to Potters Ltd for this product. The PLR was reviewed and a product licence (PL 00250/5208R) was granted to Potters Ltd on 29 May 1990. The product licence was transferred to Vifor Pharma UK Ltd on 11 July 2012 (PL 33656/0021). Vifor Pharma UK Ltd has committed to cancel PL 33656/0021 following the grant of the Traditional Herbal Registration Certificate.

This THR application was made under Article 16.c of Directive 2001/83 EC in accordance with arrangements to transfer certain herbal products with a Marketing Authorisation to a THR (according to MHRA Guidance dated January 2009). The application falls within the simplified THR application Category A, as no significant changes have been made to the formulation of the product. No new data were submitted, nor was it necessary for this application, as the data are essentially identical to those of the existing product.
PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: ECHINACEA ANGUSTIFOLIA ROOT

Scientific name of the plant: *Echinacea angustifolia* (D.C)

Plant family: Asteraceae

Synonyms of the herbal substance: Coneflower

The herbal substance is acceptable.

HERBAL PREPARATION: ECHINACEA ANGUSTIFOLIA ROOT

Drug extract ratio (DER): 100:22

Extraction solvent: Water

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

HERBAL PRODUCT: POTTER’S SKIN CLEAR TABLETS

Description and Composition of the Herbal Product

Potter’s Skin Clear Tablets are green, round, film-coated tablets. Each tablet contains: 110 mg of dry extract from *Echinacea angustifolia* root and the pharmaceutical excipients calcium hydrogen phosphate, microcrystalline cellulose, stearic acid, colloidal anhydrous silica, magnesium stearate, maltodextrin and clear film coating containing hypromellose, glycerol and hydroxypropyl cellulose. The formulation is in line with that of the already licensed product. It is, therefore, acceptable.

Manufacture

The manufacturing process is in line with that of the already licensed product and is satisfactory.

Finished Product Specification

The finished product specification is in line with that of the already licensed product and is satisfactory.

Container Closure System

Potter’s Skin Clear Tablets are stored in tamper evident polyethylene/polypropylene pots packed into a cardboard box. Pack sizes of 30, 50, 60, 84, 100, 126 and 168 tablets have been authorised, although not all pack sizes may be marketed. This type of packaging has been used to store the already licensed product and is satisfactory.

Stability

The product has a shelf-life of 3 years when the storage precautions ‘Do not store above 25°C’ and ‘Keep in the original container’ are applied. This is in line with the already licensed product and is appropriate.
Summary of Product Characteristics, product labels and Patient Information Leaflet
All product literature is in line with that of the already licensed product, with some details amended in line with other products registered under the THR scheme.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
PRECLINICAL ASSESSMENT

INTRODUCTION
No new preclinical data have been supplied with this application and none are required for an application of this type.

Assurance has been given that the results of genotoxicity testing will be provided by the renewal date of the Traditional Herbal Registration.

PRODUCT LITERATURE
All product literature is satisfactory from a preclinical point of view.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
CLINICAL ASSESSMENT

INTRODUCTION
The clinical particulars for Potter’s Skin Clear Tablets are identical to those for the already licensed product. This is satisfactory.

PRODUCT LITERATURE
All product literature is medically satisfactory.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
Potter’s Skin Clear Tablets is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type. The results of genotoxicity testing will be provided before the THR is renewed.

EFFICACY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products.

SAFETY
No new or unexpected safety concerns arose from this application.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and a THR should be granted.
POTTER’S SKIN CLEAR TABLETS

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STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Traditional Herbal Registration application on 24 October 2012
2 Following standard checks and communication with the applicant the MHRA considered the application valid on 29 October 2012
3 Following assessment of the application the MHRA requested further information relating to the dossier on 2 November 2012
4 The applicant responded to the MHRA’s requests, providing further information on the dossier on 16 November 2012
5 A THR was granted on 21 January 2013
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Potter’s Skin Clear Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film coated tablet contains:
110 mg of extract (as dry extract) from Echinacea angustifolia root (100:22)
(equivalent to 500 mg Echinacea angustifolia (D.C))
Extraction solvent: Water

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Tablet.
A green round film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used for the symptomatic relief of
minor skin conditions such as spots, pimples and blemishes, based on
traditional use only.

4.2 Posology and method of administration
For oral use only.
Adults and the elderly: Take two tablets three times a day.
Children and adolescents over 12 years: Take half the adult dose.
Not recommended for children under 12 years of age. (See section 4.4 ‘Special
warnings and precautions for use’.)
If the symptoms worsen or persist during the use of the medicinal product, a
doctor or a qualified healthcare practitioner should be consulted.
Duration of use:
Do not take for longer than 2 weeks.

4.3 Contraindications
Hypersensitivity to the active ingredients, other plants of the Asteraceae
(Compositae) family or 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.
onocological cytostatic therapy, history of organ or bone marrow transplant)
and diseases of the white blood cell system (e.g. agranulocytosis, leukaemias)
and allergic diathesis (e.g. urticaria, atopic dermatitis, asthma).
4.4 **Special warnings and precautions for use**
Do not exceed the stated dose.
If the symptoms worsen or if signs of infection are observed if symptoms do not improve during the use of the product, a doctor or a qualified health care practitioner should be consulted.
There is a possible risk of allergic reactions in sensitive individuals. Those patients should consult their doctor before using Echinacea.
There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using Echinacea.
Not recommended for children under 12 years of age because data are not sufficient and medical advice should be sought.

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**
The safety of this product during pregnancy and lactation has not been established, therefore the use of this product 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 for humans is unknown.
Studies on fertility have not been performed.

4.7 **Effects on ability to drive and use machines**
No studies have been conducted on the effects on the ability to drive or use machines.

4.8 **Undesirable effects**
Hypersensitive reactions (skin reactions, rash, urticaria, Stevens-Johnson Syndrome, angiodema of the skin, Quincke’s oedema, bronchospasm with obstruction, asthma and anaphylactic shock) have been reported.

Echinacea can trigger 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 use (more than 8 weeks). The frequency is not known.
If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9 **Overdose**
No cases of overdose have 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
Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Calcium Hydrogen Phosphate
Microcrystalline Cellulose
Stearic Acid
Colloidal Anhydrous Silica
Magnesium Stearate
Maltodextrin
Clear film coating containing hypromellose, glycerol and hydroxypropyl cellulose

6.2 Incompatibilities
None known.

6.3 Shelf life
Three years.

6.4 Special precautions for storage
Do not store above 25°C. Keep in the original container.

6.5 Nature and contents of container
Tamper evident polyethylene/polypropylene pot packed in a cardboard box:
30, 50, 60, 84, 100, 126 and 168 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal
There are no special precautions for disposal.

7 MARKETING AUTHORISATION HOLDER
Vifor Pharma UK Ltd
1 Botanic Court,
Martland Park,
Wigan,
WN5 0JZ,
UK.
Trading as: Potters, Wigan WN5 0JZ

8  MARKETING AUTHORISATION NUMBER(S)
    THR 33656/0049

9  DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
    21/01/2013

10 DATE OF REVISION OF THE TEXT
     21/01/2013
4. POSSIBLE SIDE EFFECTS:
Like all medicines this product can cause side effects, but not everyone gets them. If any of the following or other side effects occur, including allergic reactions, stop taking this product and consult your doctor or pharmacist:
• allergic reactions e.g. rash, hives, swelling of the skin due to fluid, swelling of the facial area (Quincke's oedema)
• shrinking of the airways in the lungs (bronchospasm)
• asthma and life-threatening reactions (anaphylactic shock).
Association with auto-immune diseases have been reported such as: inflammation of the brain and spinal cord, painful lumps on the shins, low blood platelet count, destruction of blood cells by antibodies (Evans Syndrome), dryness of the mouth and eyes with renal tubular dysfunction (Sjorgen syndrome).
A decrease in the number of white blood cells (Leucopenia) may occur in long-term use (more than 8 weeks).

5. HOW TO STORE POTTER’S SKIN CLEAR TABLETS:
Keep out of the reach and sight of children.
Do not use Potter’s Skin Clear Tablets after the expiry date. The expiry date is printed on the label and base of the carton.
Do not store above 25°C. Store in the original packaging.
Return any unused medicine to your pharmacist for safe disposal.

6. FURTHER INFORMATION:
Each film coated tablet contains: 110 mg Dry Extract Echinacea angustifolia root (100:22) (equivalent to 500 mg Echinacea angustifolia (DC))
Extraction solvent: Water.
This product also contains:
Calcium Hydrogen Phosphate, Microcrystalline Cellulose, Stearic Acid, Colloidal Anhydrous Silica, Magnesium Stearate, Maltodextrin, Clear film coating containing hypromellose, glycerol and hydroxypropyl cellulose.
Potter's Skin Clear Tablets are green round film-coated tablets and are available in containers of 60 tablets.

Traditional Herbal Registration Holder and Manufacturer:
Potters, Wigan WN5 0JJ
Traditional Herbal Registration number:
THR 33656/0049

Making medicines safer:
You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard
Alternatively you can get a paper Yellow Card form from your doctor's surgery or a pharmacy, or call freephone 0808 100 3352 (available 10am-3pm, Monday to Friday).
For further information, call 01202 449752
If you would like a version of this leaflet in an alternative format, please call 01942 219960
Product code: SKICOLEA
Leaflet last revised: 04/12/2012
This medicine is available without prescription. However, you still need to take Potter's Skin Clear Tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or pharmacist if your symptoms worsen or do not improve after 2 weeks.
- If you experience any of the side effects listed in this leaflet, or if you notice any other side effects, please consult your doctor or pharmacist.

IN THIS LEAFLET:
1. What Potter's Skin Clear Tablets are and what they are used for
2. Before you take Potter's Skin Clear Tablets
3. How to take Potter's Skin Clear Tablets
4. Possible side effects
5. How to store Potter's Skin Clear Tablets
6. Further information

1. WHAT POTTER'S SKIN CLEAR TABLETS ARE AND WHAT THEY ARE USED FOR:
Potter's Skin Clear Tablets are a traditional herbal medicinal product used for the symptomatic relief of minor skin conditions such as spots, pimples and blemishes, based on traditional use only.

Containing extract of Echinacea (Echinacea angustifolia).

For full details, see Section 6.

2. BEFORE YOU TAKE POTTER'S SKIN CLEAR TABLETS:
Do not take Potter's Skin Clear Tablets:
- if you are allergic to any of the ingredients or other plants of the Asteraceae/Compositae family e.g. daisy, artichokes or marigolds
- if you suffer from: frequent allergic reactions such as hives, eczema, asthma, tuberculosis; sarcoidosis; auto immune diseases e.g. collagenosis, multiple sclerosis; conditions which decrease your resistance to infection e.g. HIV infection or AIDS; while blood cell disorders e.g. anaemia, leukaemia
- if you are on therapy to reduce natural response to infection (e.g. chemotherapy, radiotherapy, history of organ or bone marrow transplant)
- if you are pregnant or breastfeeding
- if you are under 12 years of age
- if you are taking immunosuppressant medications such as ciclosporin and methotrexate.

Take special care:
- if there is a family history of allergic reactions
- Echinacea can trigger auto-immune disease.

Taking other medicines:
Please ask your doctor or pharmacist for advice if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding:
You should not use Potter's Skin Clear Tablets if you are pregnant or breastfeeding because there is no evidence that it is safe to do so.

3. HOW TO TAKE POTTER'S SKIN CLEAR TABLETS:
It is important that you follow these instructions carefully.

For oral use:
Adults, the elderly and children over 12 years: Take two tablets three times a day.
Do not exceed the stated dose.
Do not use the product for more than 2 weeks.
If your condition worsens or symptoms persist for more than 2 weeks, or signs of skin infection are observed, consult your doctor or pharmacist.

If you take too many Potter's Skin Clear Tablets:
Stop taking the medicine and consult your doctor or pharmacist.

If you forget to take Potter's Skin Clear Tablets:
If you miss a dose, take your next dose at the usual time. Do not take two doses at the same time to make up for a missed dose. Always consult your doctor or pharmacist if you need further advice.
LABELLING

Label:

![Label Image]
Carton: