

# **Echinaforce Hot Drink Cold & Flu Echinacea concentrate for oral solution**

**THR 13668/0031**

**UKPAR**

## **TABLE OF CONTENTS**

<b>Lay summary</b>	<b>Page 2</b>
<b>Scientific discussion</b>	<b>Page 3</b>
<b>Steps taken for assessment</b>	<b>Page 12</b>
<b>Summary of Product Characteristics</b>	<b>Page 13</b>
<b>Product Information Leaflet</b>	<b>Page 14</b>
<b>Labelling</b>	<b>Page 15</b>

# **ECHINAFORCE HOT DRINK COLD & FLU ECHINACEA CONCENTRATE FOR ORAL SOLUTION**

**THR 13668/0031**

## **LAY SUMMARY**

The Medicines and Healthcare Products Regulatory Agency (MHRA) granted Bioforce (UK) Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Echinaforce Hot Drink Cold & Flu Echinacea concentrate for oral solution (Traditional Herbal Registration number: THR 13668/0031) on 1 October 2014. Echinaforce Hot Drink Cold & Flu Echinacea concentrate for oral solution is available without prescription and can be bought from pharmacies and other outlets.

The active ingredients in Echinaforce Hot Drink Cold & Flu Echinacea concentrate for oral solution come from the root and herb of the *Echinacea purpurea* plant. Echinaforce Hot Drink Cold & Flu Echinacea concentrate for oral solution is a traditional herbal medicinal product used to relieve the symptoms of the common cold and influenza type infections based on traditional use only.

This registration is based exclusively upon the longstanding use of *Echinacea purpurea* 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 a 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.

**ECHINAFORCE HOT DRINK COLD & FLU ECHINACEA CONCENTRATE  
FOR ORAL SOLUTION**

**THR 13668/0031**

**SCIENTIFIC DISCUSSION**

TABLE OF CONTENTS

Introduction	Page 4
Pharmaceutical assessment	Page 5
Non-clinical assessment	Page 8
Clinical assessment	Page 9
Overall conclusions and risk assessment	Page 11

## **INTRODUCTION**

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Echinaforce Hot Drink Cold & Flu Echinacea concentrate for oral solution (THR 13668/0031) to Bioforce (UK) Ltd on 1 October 2014. This product is on the general sales list (GSL).

This application was submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme. Echinaforce Hot Drink Cold & Flu Echinacea concentrate for oral solution is a traditional herbal medicinal product used to relieve the symptoms of the common cold and influenza type infections based on traditional use only.

There is sufficient evidence to demonstrate use of *Echinacea purpurea* root and herb for at least 30 years, of which at least 15 years have been in an EU Member State. A satisfactory review of the available safety data on these herbal substances has also been provided, together with an Expert Safety Report supporting the proposed product.

## PHARMACEUTICAL ASSESSMENT

### **HERBAL SUBSTANCES: *ECHINACEA PURPUREA* ROOT AND HERB**

**Scientific name of the plant:** *Echinacea purpurea* (L.) Moench.

**Plant family:** Asteraceae

#### **Manufacture of Herbal Substances**

The *Echinacea purpurea* plants are cultivated in central Europe under organic conditions (according to EC Directive 2092/91).

The roots are mechanically harvested between September and November in the second year of growth or later. They are washed with drinking water to remove the soil and dripped dry. The fresh material is chopped and transferred into maceration containers. The herb is mechanically harvested during flowering time between July and August (old crop) and September (first year crop).

The supplier of the herbal substances has provided confirmation that they are produced in accordance with the principles of Good Agricultural and Collection Practice (GACP).

#### **Control of Herbal Substances**

Suitable specifications are used to control the *Echinacea purpurea* root and herb.

#### **Container Closure System**

Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

#### **Stability**

No data were provided. This is acceptable as the guideline requires stability testing data for the herbal preparation and the herbal product in the application documents and not for the herbal substances.

### **HERBAL PREPARATIONS: *ECHINACEA PURPUREA* ROOT AND HERB EXTRACT**

**Extract solvent:** Ethanol 65% V/V

**Drug extract ratios (native):** 1:11-12 (root)  
1:12-13 (herb)

#### **Manufacture of Herbal Preparations**

Satisfactory descriptions of the manufacturing processes of the herbal preparations and flow diagrams have been provided. The in-process controls are satisfactorily detailed. Certificates of Analysis for all materials used in the manufacture of the herbal preparations have been provided.

MHRA PAR; ECHINAFORCE HOT DRINK COLD & FLU ECHINACEA CONCENTRATE 5  
FOR ORAL SOLUTION, THR 13668/0031



### **Control of Herbal Product**

The finished product specifications are satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification.

### **Container Closure System**

The oral solution is stored in a 100 ml amber glass bottle with a white pilfer-proof PE-HD screw cap and white PE-LD spout. A measuring spoon with a 5 ml measure is supplied with each pack.

Suitable specifications have been provided by the packaging suppliers and it has been confirmed that all primary packaging materials comply with current requirements.

### **Stability of Herbal Product**

Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, product shelf-lives of 30 months for product stored in unopened containers and of 1 month once the containers are first opened are acceptable.

### **Pharmaceutical Expert**

The Quality Overall Summary has been written by an expert with suitable experience.

### **Product Literature**

All product literature is satisfactory.

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.

### **CONCLUSION**

There are no objections to granting of a Traditional Herbal Registration from a quality point of view.

## **NON-CLINICAL ASSESSMENT**

### **NON-CLINICAL OVERVIEW**

An Expert Safety Report was provided, which includes reviews of some non-clinical data. The Expert Safety Report was written by a suitably qualified professional. In addition, the Committee on Herbal Medicinal Products (HMPC) Community Monographs and assessment reports for *Echinacea purpurea* root and herb adequately cover the non-clinical safety issues for these herbal preparations.

Due to a shortage of published data on *Echinacea purpurea* root and herb, it is not possible to assess if the safety package for the phytochemical constituents of this active ingredient is acceptable to the standards of today's GLP and safety testing requirements. However, the information supplied demonstrating traditional use is acceptable and thus the lack of provision of a complete standard safety package is acceptable and in compliance with guideline EMEA/HMPC/32116/05.

*Echinacea purpurea* herb showed no toxicity in single-dose toxicity, repeated-dose toxicity and genotoxicity studies. Tests on reproductive toxicity and on carcinogenicity have not been performed. Tests on reproductive toxicity, genotoxicity and on carcinogenicity have not been performed with *Echinacea purpurea* root.

The overview submitted in support of this application is satisfactory.

### **SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

The SmPC for this product is satisfactory from a non-clinical point of view.

### **ENVIRONMENTAL RISK ASSESSMENT**

An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

### **CONCLUSION**

There are no objections to granting of a Traditional Herbal Registration from a non-clinical point of view.



## **CLINICAL ASSESSMENT**

### **INDICATIONS**

The applicant has submitted the following therapeutic indications:

“Traditional herbal medicinal product used to relieve the symptoms of the common cold and influenza type infections based on traditional use only.”

These indications are acceptable.

### **POSOLOGY AND METHOD OF ADMINISTRATION**

The applicant has submitted the following:

“For oral use only.

Adults and children over 12 years:

Days 1-3: Take 5 ml diluted in hot water five times daily

Days 4-10: Take 5 ml diluted in hot water three times daily

Dilute in hot water before use.

Not recommended for use in children under 12 years of age (See section 4.4 Special warnings and precautions for use).

Start at first signs of common cold. Do not use the product for more than 10 days. If symptoms worsen during the use of the product or persist for more than 10 days, a doctor or qualified healthcare practitioner should be consulted.”

This is acceptable.

### **EFFICACY**

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

### **EVIDENCE OF TRADITIONAL USE**

Article 16 c 1 (c) requires the applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the European Community.

The applicant has provided a bibliographic review as evidence for the use of *Echinacea purpurea* root and herb within the EU for a period exceeding 30 years. The requirements of the Directive are, therefore, considered to be met.

### **SAFETY REVIEW**

Article 16 c 1 (d) requires the applicant to provide a bibliography of the safety data together with an expert report.

A safety review has been provided as well as an Expert Safety Report written by a suitably qualified professional. The HMPC monograph also covers the relevant safety issues.

**PRODUCT LITERATURE**

The SmPC, PIL and labelling for this product are medically satisfactory.

**CONCLUSION**

There are no objections to granting of a Traditional Herbal Registration from a clinical point of view.

## **OVERALL CONCLUSION AND RISK ASSESSMENT**

### **QUALITY**

The quality data submitted with this application are satisfactory.

### **NON-CLINICAL**

Satisfactory genotoxicity data are provided and are satisfactory. No other non-clinical data are needed this application.

### **EFFICACY AND SAFETY**

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

The applicant has provided a bibliographic review which shows ample evidence for the use of *Echinacea purpurea* root and herb within the EU for a period exceeding 30 years and a satisfactory review of the safety data has been provided.

Furthermore, the HMPC monograph for *Echinacea purpurea* root and herb adequately covers the evidence for traditional use of the extract in the product under assessment for at least 30 years and the safety issues associated with *Echinacea purpurea* root and herb.

The SmPC, PIL and labelling are satisfactory.

### **RISK ASSESSMENT**

The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and a Traditional Herbal Registration may be granted.

**ECHINAFORCE HOT DRINK COLD & FLU ECHINACEA CONCENTRATE  
FOR ORAL SOLUTION**

**THR 13668/0031**

**STEPS TAKEN FOR ASSESSMENT**

- 1 The MHRA received the Traditional Herbal Registration application on 8 August 2013
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 10 September 2013
- 3 Following assessment of the application the MHRA requested further information relating to the clinical dossier on 10 February 2014 and the quality dossier on 28 April 2014
- 4 The applicant responded to the MHRA's request, providing further information on the clinical and quality dossiers on 31 July 2014
- 5 A THR was granted on 1 October 2014

## **SUMMARY OF PRODUCT CHARACTERISTICS**

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

## **PATIENT INFORMATION LEAFLET**

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

## LABELLING

### Label:

Echinaforce Hot Drink Concentrate is a traditional herbal medicinal product used to relieve the symptoms of cold and flu. This is based on traditional use only.

**Directions for use:**  
**To be made into a hot drink by diluting in hot water before use.**

**Adults and children over 12 years:**  
**Days 1 to 3:** Take 5 ml diluted in hot water five times daily.  
**Days 4 to 10:** Take 5 ml diluted in hot water three times daily.

For oral use only. Read leaflet before use. Keep out of the sight and reach of children. Store below 25°C. After opening, store in the refrigerator (below 8°C). Use within 1 month of opening.

**Traditional Herbal Registration Holder:**  
Bioforce (UK) Ltd, Irvine, UK KA11 5DD  
THR 13668/0031

**100 ml e**



The image shows the packaging for A.Vogel Echinaforce Hot Drink Concentrate. The top part is green with the A.Vogel logo. Below that, the product name 'Echinaforce Hot Drink' is written in a serif font, with 'Cold & Flu' in a purple oval. Underneath, it says 'Echinacea concentrate for oral solution'. The central image features a pink Echinacea flower and a cluster of dark berries. At the bottom, there is a barcode and the text 'tech.data' in a red box.

**Ingredients:**  
5 ml of concentrate contains 1,140 mg of extract (as tincture) of fresh *Echinacea purpurea* (L.) Moench herb (1:12-13) and 60 mg of extract (as tincture) of fresh *Echinacea purpurea* (L.) Moench root (1:11-12). Extraction solvent: Ethanol 65% V/V. This product contains sucrose and ethanol. See leaflet for further information.

Safety Sealed Bottle. If ring at bottom of cap is missing or separated, do not use.

EXP :  
Batch :

tech.data

30315L1 09116000/080914

**Carton:**

