LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Echinaforce, tablet

***Echinacea purpurea* (L.) Moench (purple coneflower) herba recens, extract**
and
***Echinacea purpurea* (L.) Moench (purple coneflower) radix recens, extract**

Asp. No: 2008-1043

This module reflects the scientific discussion for the approval of Echinaforce, tablet. The procedure was finalised at 7 October 2009. For information on changes after this date please refer to the module 'Update'.

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LAY SUMMARY

The Medical Products Agency (Läkemedelsverket) has granted Svenska Bioforce AB, Sweden, a traditional-use registration for the herbal medicinal product Echinaforce tablets. This product is available without prescription and can be bought from pharmacies and other outlets.

Echinaforce is traditionally used for the relief of symptoms of common cold. The active ingredients are two dry ethanolic extracts from fresh roots respectively fresh herb of *Echinacea purpurea* (L.) Moench (purple coneflower, röd solhatt). This registration is based exclusively upon evidence of traditional use of *Echinacea purpurea* as a herbal medicinal product and not upon data generated from clinical trials. For traditional herbal medicinal products there is no requirement to scientifically prove the effect; adequate evidence of traditional use is sufficient.

The chemical/pharmaceutical quality of the product is acceptable and no new or unexpected safety concerns have been identified during the assessment. It was therefore decided that Echinaforce, tablets could be registered as a traditional herbal medicinal product.

I. INTRODUCTION

Svenska Bioforce AB has applied for a traditional use registration for Echinaforce, tablet. The application was submitted under Article 16a traditional use registration for herbal medicinal product of the Directive 2001/83 EC, as amended.
The application is a national application for Sweden.

The active substances are:
Echinacea purpurea (L.) Moench fresh herb, dry extract (17-34:1), ethanol 57 % (m/m)
Echinacea purpurea (L.) Moench fresh root, dry extract (19-33:1), ethanol 57 % (m/m)

Echinaforce, tablet, was first authorised as a natural remedy in 2004. With the new legislation regarding (traditional) herbal medicinal products the product was reclassified as a traditional herbal medicinal product in 2009.

For approved indications, see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Echinaforce is presented in the form of tablets containing 5.9 mg of the active substance *Echinacea purpurea* (L.) Moench fresh herb, dry extract (17-34:1), ethanol 57 % (m/m), corresponding to 140 mg of fresh herb of purple coneflower, and 0,3 mg of the active substance *Echinacea purpurea* (L.) Moench fresh root, dry extract (19-33:1), ethanol 57 % (m/m), corresponding to 8 mg of fresh root of purple coneflower.

The excipients are:
Lactose monohydrate, pregelatinised starch and magnesium stearate.

All manufacturers involved in the production operate in accordance with EU-GMP (Good Manufacturing Practice), or where relevant, GACP (Good Agricultural and Collection Practice).

II.2 Drug Substance

The herbal substances *Echinacea purpurea* (L.) Moench fresh herb and *Echinacea purpurea* (L.) Moench fresh root are controlled using in-house monographs based on the Ph. Eur. monographs for the same dried substances.

The plants used are cultivated in Central Europe. Relevant information on growing conditions and controls of the herbal substance (such as residues of heavy metals and pesticides as well as microbiological quality) has been provided. The plant material is cut (the roots also washed) before being extracted with ethanol. Both extracts are made separately but later mixed to an intermediate product in the ratio 95:5 (herb liquid extract:root liquid extract) and during the manufacturing of the finished product concentrated and dried.

The manufacturing process has been adequately described and satisfactory specifications have been provided for starting materials and the solvents.

The active substances' specifications include relevant tests and the limits for impurities have been justified. The analytical methods applied are suitably described and validated.

Stability studies under ICH conditions have been conducted.

II.3 Medicinal Product

Echinaforce, tablet is formulated using excipients described in the current Ph. Eur., except for pregelatinised starch which has an in-house monograph. The magnesium stearate is of vegetable origin and the lactose monohydrate is derived from food grade cow's milk, sourced from healthy animals under the same conditions as milk collected for human consumption.

The manufacturing process has been sufficiently described and critical steps identified. Results from the process validation studies confirm that the process is under control and ensure both batch to batch reproducibility and compliance with the product specification.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies under ICH conditions have been performed and data presented support the shelf life claimed in the SmPC.

III. NON-CLINICAL AND CLINICAL ASPECTS

III.1 Introduction

The Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency (EMA) has issued a Community monograph on *Echinacea purpurea* herba and *Echinacea purpurea* radix. The extracts in Echinaforce, tablet are partially covered by the HMPC monographs. The reader is referred to the Community monographs and the pertinent assessment reports for details.

The product range Echinaforce has been in use in the Community for more than 50 years.

III.2 Non-clinical aspects

The applicant has collected available information from the literature in the areas of non-clinical pharmacology and toxicology. This information has been assessed by the MPA and no signals of non-clinical safety concern have been identified. The exact mechanism of action of extracts from *Echinacea purpurea* herb respectively root in relation to their traditional medicinal use cannot be considered clarified.

A product/extract specific study on mutagenic activity has been performed. The extract has been shown not to be mutagenic in Ames test.

Based on the non-clinical information, both from the literature and the product specific study, no objections are raised to the approval of ethanolic extracts of *Echinacea purpurea* as active ingredients in a traditional herbal medicinal product.

III.3 Ecotoxicity/environmental risk assessment

Echinaforce is a traditional herbal medicinal product. According to "Guideline on the environmental risk assessment of medicinal products for human use" (EMEA/CHMP/SWP/4447/00), (traditional) herbal medicinal products are exempted from the obligation to present an environmental risk assessment due to the nature of their constituents.

III.4 Clinical aspects

Results of clinical trials concerning clinical efficacy and safety are not required for the registration of a traditional herbal medicinal product.

III.5 Traditional use

The medicinal use of *Echinacea purpurea,* herb and root has a long tradition exceeding 50 years in the Community. It is mainly used for the relief of symptoms of common colds. The recommended dosage of Echinaforce, tablet is in the same range as the ones used traditionally and listed in the literature.

The applicant has provided a bibliographic review which shows sufficient evidence for the medicinal use of *Echinacea purpurea* throughout a period of at least 30 years, including at least 15 years within the Community. Hence, the requirement of traditional use according to Directive 2004/24/EC is considered fulfilled.

III.6 Clinical safety

The safety profile of Echinaforce, tablet is well established both from clinical studies and from its use for over 50 years as a marketed medicinal product in many countries world-wide with usage by many millions of patients.

In the assessment report pertaining to the Community monograph on *Echinacea purpurea,* herb, hypersensitivity to plants of the Asteraceae family is mentioned as well as severe immune reactions for atopic patients. As with all immunostimulants, *Echinacea* is not recommended in cases of progressive systemic disorders and autoimmune diseases immunodeficiencies, immunosuppression and diseases of the white blood cell system such as tuberculosis, leukoses, collagenoses, multiple sclerosis, AIDS or HIV-infections
The majority of adverse events reported are related to hypersensitivity reactions like rashes including urticaria.

Information about the large sales volumes of products containing the Echinaforce extracts and a very long history of traditional use indicate that Echinaforce, tablet is generally safe.

As no safety data on use in children are available, products containing *Echinacea purpurea,* herb and/or root *cannot* be recommended for use in children aged 1 to 12 years. The use is contraindicated for children below the age of 1 year.

Due to the lack of safety data, the use of products containing *Echinacea purpurea,* herb and/or root during pregnancy and lactation is not recommended.

Based on the clinical safety information available, no objections are raised to the approval of Echinaforce, tablet as a traditional herbal medicinal product.

IV. OVERALL CONCLUSION, RISK ASSESSMENT AND RECOMMENDATION

For Echinaforce, tablet, the handling, manufacture and quality control of raw materials, active substance and finished product are in line with GMP and pharmacopoeial requirements. The applicant has shown that the chemical/pharmaceutical quality is acceptable and can confirm that the process is under control and ensures both batch reproducibility and compliance with the product specification.

The applicant has provided evidence that the extracts have had a medicinal use for at least 30 years, including at least 15 years within the Community.

No signals of preclinical or clinical safety concern have been identified under normal conditions of use.

Echinaforce, tablet can be recommended for registration as a traditional herbal medicinal product.

V. APPROVAL

Echinaforce, tablet was approved in the national procedure on 7 October 2009.

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Public Assessment Report – Update

Scope	Procedure number	Product Information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached
Complete re-formulation of the tablet. Tablet weigh and dimensions have changed. Excipients lactose monohydrate and pregelatinised starch are removed and sorbitol, mannitol, croscarmellose sodium, medium-chain triglycerides and sucrose laurate are added The quantity of excipient magnesium stearate is reduced.	5.4.3-2025-035374	SmPC PL LAB	2025-05-19	2025-11-06	approval	Y/N (version)

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