Ravimiamet
State Agency of Medicines

Hinnangu kokkuvõte

27.01.2014 anti müügiluba KRKA d.d., Novo mesto ravimile Herbion Islandi Käokõrv, 6 mg 1 ml, siirup.

Müügiluba taotleti rahvusliku protseduuri kaudu.

Herbion Islandi Käokõrva siirup sisaldab Islandi käokõrva paksekstrakti. Herbion Islandi Käokõrv on traditsiooniline taimne ravim, mille näidustus põhineb pikaajalisel kasutamiskogemusel, mida soovitatakse kasutada kurguärrituse sümptomaatiliseks leevendamiseks kuiva köha ning suu- ja neelupõletiku korral. Herbion Islandi Käokõrv kuulub ravimite rühma mida nimetatakse ekspektorantideks.

Tegemist on käsimüügiravimiga.

Ravimile anti müügiluba, kuna Herbion Islandi Käokõrv kasutamisest oodatav kasu ületab võimalikud riskid.

Avalik hinnanguaruanne on leitav järgnevatelt lehekülgedelt.

Public Assessment Report

Scientific discussion

Herbion Islandi Käokõrv
Herbion Iceland Moss syrup

Date: 23.04.2014

This module reflects the scientific discussion for the approval of Herbion Islandi Käokõrv. The procedure was finalised at 27.01.2014. For information on changes after this date please refer to the module 'Update'.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data Estonia has granted a marketing authorisation for Herbion Islandi Käokõrv, 6 mg/ml, syrup, from KRKA d.d., Novo Mesto.

The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use as demulcent to treat irritation or inflammation of the oral and pharyngeal mucosa and accompanying dry cough.
A comprehensive description of the indications and posology is given in the SmPC.

The marketing authorisation has been granted pursuant to Article 16a, traditional use registration for herbal medicinal product, of Directive 2001/83/EC, as amended.

II. QUALITY ASPECTS

II.1 Introduction

Herbion Islandi Käokõrv 1 ml of syrup contains 6 mg of Iceland moss soft extract (*Cetraria islandica* (L.) Acharius s.l., *thallus*), which is equivalent to 96–108 mg of Iceland moss.
Herbion Islandi käokõrv contains the following excipients: liquid sorbitol, xanthan gum, sodium benzoate, citric acid monohydrate, lemon flavour and purified water.

Container system is brown glass bottle, hydrolytic Class III (Ph. Eur.), plastic cap, measuring spoon: 150 ml of syrup, in a box.

II.2 2.2 Drug Substance

Herbal substance: whole or cut, dried thallus of *Cetraria islandica* (L) Acharius s.l.
Herbal substance is of European origin and the plant is collected in accordance with Good Agricultural and Collection Practice (GACP) guidelines.
The monograph of Iceland moss is included in the Ph. Eur. The quality is controlled accordingly.

Herbal preparation: Iceland moss soft extract is produced by extraction of Iceland moss (Ph. Eur.) with water. Ratio of herbal drug to native extract (DER) is 16-18:1
The final product is 100% native extract.
Iceland moss soft extract is classified, according to the monograph „Extracts“ (*Extracta*) issued in the European Pharmacopoeia as „Other extracts“. Manufacturing process and analytical procedures are sufficiently described and set acceptance criteria together with the proposed re-test period are considered adequate.

II.3 Medicinal Product

Herbion Islandi Käokõrv 1 ml of syrup contains 6 mg of Iceland moss soft extract (*Cetraria islandica* (L.) Acharius s.l., *thallus*), which is equivalent to 96–108 mg of Iceland moss.
The development of the product has been described, the choice of excipients is justified and their functions explained. The excipients used, except lemon flavour, are of Pharmacopoeial quality and comply with the Ph. Eur.
The manufacturing procedure and in process controls are performed to guarantee the quality of the drug product.
The drug product`s specifications are considered acceptable. Batch analysis has been provided for 3 batches and results are within proposed specifications.

The drug product is packed in brown glass bottle, hydrolytic Class III (Ph. Eur.), plastic cap, measuring spoon: 150 ml of syrup, in a box.
Stability studies have been performed according to ICH guideline. The proposed shelf-life of the drug product is 24 months, the proposed shelf-life after first opening of container is 3 months with the special storage condition: “do not refrigerate”.

III. NON-CLINICAL ASPECTS

III.1 Ecotoxicity/environmental risk assessment (ERA)

An environmental risk assessment is not required for herbal medicinal products.

III.2 Discussion on the non-clinical aspects

The application is traditional use registration for herbal medicinal product Herbion Islandi käokõrv, syrup. The preparation Herbion Islandi käokõrv, syrup contains soft aqueous extract of *Lichen islandicus* (*Cetraria islandica*) as pharmaceutical ingredient which has been in medicinal use throughout a period of at least 30 years as herbal remedy against catarrhal disorders.
Herbal preparations containing iceland moss are broadly used as demulcents to treat irritation or inflammation of the oral and pharyngeal mucosa and accompanying dry cough as an aqueous extract. Iceland moss is positively evaluated in the scientific monographs by the German Commission E, the ESCOP and the WHO monographs.

IV. CLINICAL ASPECTS

IV.1 Introduction

Iceland moss belongs to a group of medicines called cough suppressants. The product is a traditional herbal medicinal product for treatment in the specified indication exclusively based upon long-standing use as a demulcent on relieving symptoms associated with milder inflammations and irritations of the oral and pharyngeal mucous membrane which result in minor ailments of throat irritation and hence dry cough. Iceland moss syrup contains high amounts of water-soluble mucilages, which cover, protect and moisten the oral and pharyngeal mucosa, soothing its irritability and relieving dry cough.
The indications of the herbal medicinal product containing extract of the medicinal plants, such as iceland moss, are listed in authoritative European monographs.

IV.2 Discussion on the clinical aspects

This is an application for a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.
No new pharmacokinetic and pharmacodynamic studies have been performed.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

User consultation
A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to the product of the Herbion ivy syrup (Krka d.d. Novo Mesto) which was a medicine from the same drug class and with the same pharmaceutical form, but somewhat different indication profile and posology.
Layout, structure and language of these leaflets were identical.

The leaflets were nearly identical in all basic bridging criteria.
The bridging report submitted by the applicant has been found acceptable.

The benefit/risk ratio is considered positive and the application for Herbion Islandi Käokõrv, syrup is recommended for approval.