IPAR

Public Assessment Report for a
Homeopathic Medicinal Product
for Human Use

Coldenza 6C Tablets
Gelsemium sempervirens (GHP)

HOA1149/005/001
HOA holder: A Nelson & Co Limited

Date December 2016

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I INTRODUCTION

Specific provisions were introduced for homeopathic medicinal products (HMPs) in accordance with the Directive (2001/83/EC), as amended. The national regulations, the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) which implement this Directive came into force on 23rd July 2007. Consequently the HPRA has established the National Rules Scheme for Homeopathic Medicinal Products.

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a homeopathic marketing authorisation for a specific homeopathic medicinal product for human use. It is made available by the HPRA for the purposes of providing information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of EC Directive 2001/83/EC, as amended by Directive 2004/27/EC and Directive 2004/24/EC. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA, leading to the approval of the homeopathic medicinal product for marketing in Ireland.

Based on the review of the data on quality, safety and homeopathic use, the HPRA has granted a homeopathic marketing authorisation for Coldenza 6C Tablets, containing Gelsemium sempervirens.

This application was submitted as a standard application according to Article 16.2 of Directive 2001/83/EC, as amended, and as part of the National Rules Authorisation Scheme.

The Summary of Product Characteristics (SmPC) for this homeopathic medicinal product is available on the HPRA's website.

II QUALITY ASPECTS

This application is for Coldenza 6C Tablets. The active ingredient of Coldenza is derived from the plant Gelsemium sempervirens.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Gelsemium sempervirens 6C

Excipient(s) with known effect:

Lactose 79.21% w/w

Sucrose 19.27% w/w

II.1 S.1 Homeopathic raw material

The homeopathic raw material specification for Gelsemium sempervirens is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.2 S.2 Homeopathic stock

The homeopathic stock Gelsemium sempervirens is described in an Official pharmacopoeia of a Member State, the German Homeopathic Pharmacopoeia, and is manufactured in accordance with the principles of good manufacturing practice (GMP).

The homeopathic stock specification is considered adequate to control the quality and meets current pharmacopoeial

requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition

Coldenza consists of biconvex circular white to off-white tablets.

Composition of the medicinal product.

Gelsemium sempervirens 6C

Lactose monohydrate

Sucrose

Stearic acid

Magnesium stearate

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of GMP at suitably qualified manufacturing sites.

P.4 Control of Other Substances (Excipients/*Ancillary Substances)*

All ingredients comply with Ph. Eur. and are adequately controlled.

Adventitious agent safety

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies.

Scientific data has been provided *for* Coldenza and *compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products has been satisfactorily demonstrated.*

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for the dosage form tablets, and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production site(s) have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

The product is presented as Aluminium/PVC blister strips packed in a cardboard carton

Pack size: 72 tablets

Evidence has been provided that packaging type complies with Ph. Eur./EU legislation for use with foodstuffs requirements.

P.7 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines demonstrating the stability of the product for 3 years when stored 'not above 25°C', storage conditions of SmPC.

II.4 Conclusion on quality

The important quality characteristics of the product are well-defined and controlled. Satisfactory pharmaceutical documentation has been provided, assuring consistent quality of Coldenza 6C Tablets.

III NON-CLINICAL ASPECTS

Product *Coldenza 6C Tablets* is a homeopathic medicinal product as defined by Article 16 of Directive 2001/83/EC, as amended.

No preclinical studies have been submitted. This is acceptable for this type of application according to the regulations (S.I. 540 of 2007). The product Coldenza 6C Tablets conforms to subparagraph 11.3 of the regulations and therefore is deemed appropriate for the proposed use.

An expert report on safety has been provided which includes an appropriate review of the available literature. Overall the information presented demonstrating homeopathic use is considered to be *acceptable*.

An environmental risk assessment is not required for homeopathic medicinal products as they contain highly dilute active ingredients and therefore pose no environmental risk.

IV CLINICAL ASPECTS

There is no requirement under the National Rules Scheme to prove scientifically that the product is efficacious, the authorisation is based exclusively upon the use of Coldenza 6C Tablets as a homeopathic medicine and not upon data generated from clinical trials.

Article 16. Directive 2001/83/EC provides for Member States to introduce or retain in their territory specific rules for the toxicological and pharmacological tests and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practised in the Member State. Accordingly, the national regulations, the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) which implement this Directive lays down criteria under Article 11 whereby a homeopathic medicinal product may be authorised under the National Rules. With regard to homeopathic use data, the requirements of Article 11 have been met.
The efficacy of this homeopathic medicinal product is plausible on the basis of use and experience.
The indication proposed for Coldenza 6C Tablets of: A Homeopathic Medicinal product used within the homeopathic tradition for the symptomatic relief of colds and related flu-like symptoms, is in line with homeopathic indications recorded for the active ingredient Gelsemium sempervirens and hence, compatible with the requirements of the regulations (S.I. No. 540 of 2007).

IV.2 Clinical Safety

In accordance with Article 11.3 the applicant has provided a bibliographic review of the safety data together with an expert report.
There are no safety issues pertaining to the use of this product as proposed. In addition treatment is being recommended for a maximum of 7 days. This is in accordance with the use of the product for mild self-limiting conditions not requiring the intervention of a Medical practitioner. The warning *'If the symptoms worsen, if fever (high temperature) is experienced, or if symptoms do not improve after 7 days, a doctor or qualified healthcare practitioner should be*

consulted.', is present on the packaging.

Additionally the following are included on the SPC, label and leaflet as appropriate.

Contraindications
Hypersensitivity to Gelsemium sempervirens or any of the excipients.

Special warnings and precautions for use
Do not exceed the stated dose

If symptoms worsen, if fever (high temperature) is experienced, or if symptoms do not improve after 7 days, a doctor or qualified healthcare practitioner should be consulted.

This product is not recommended for use in children under 12 years of age and medical advice should be sought.

Contains lactose and sucrose - Patients with rare hereditary problems of fructose intolerance, galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrose-insomaltese insufficiency should not take this medicine.

The safety of the homeopathic product has been demonstrated according to the criteria as laid down in Article 11.3 (*S.I. No. 540 of 2007).*

In conclusion, this product proves not to be harmful in the specified conditions of use based on the review of safety data, expert report and additional data provided.

IV.3 Pharmacovigilance

It should be noted that in accordance with Article 16 of Directive 2001/83/EC, as amended, the pharmacovigilance requirements described in Articles 101- 108 of Directive 2001/83/EC, as amended, also apply in respect of homeopathic medicinal products.
The Pharmacovigilance system as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

V OVERALL CONCLUSIONS

The product Coldenza 6C Tablets is manufactured by Nelsons using the Pharmacopoeial (GHP) active ingredient Gelsemium sempervirens and excipients according to Ph.Eur. Manufacturing processes are well described and controlled and appropriate for this type of oral homeopathic product. Production is carried out according to GACP/GMP as applicable.

The important quality characteristics of the product are well-defined and controlled. Satisfactory pharmaceutical documentation has been provided, assuring consistent quality of Coldenza 6C Tablets.

The product Coldenza 6C Tablets contains the active ingredient Gelsemium sempervirens which is controlled by a monograph in the GHP. The active is highly diluted to 6C in the finished product and adheres to the legislation with respect to safety requirements. All excipients in Coldenza are Ph.Eur and appropriate for this type of medicinal product. Therefore this product is considered to be safe for use in accordance with the terms of Article 11 of S.I. 540 of 2007.

Coldenza 6C Tablets has been proposed as a treatment for colds and flu: (*A Homeopathic Medicinal product used within the homeopathic tradition for the symptomatic relief of colds and related flu-like symptoms*.).

Homeopathic literature and provings support the use of the active ingredient Gelsemium for this indication. Since colds and flu are considered to be mild self-limiting conditions they are suitable for treatment by this class of homeopathic product in accordance with the National Rules (S.I. 540 of 2007). In addition treatment is being recommended for a maximum of 7 days.

The HPRA, on the basis of the data submitted, considered that Coldenza 6C Tablets demonstrated adequate evidence of homeopathic use for the approved indication(s) and no new preclinical or clinical safety concerns have been identified.

A homeopathic authorisation for Coldenza 6C Tablets is granted.