IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

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 marketing authorisation for a specific medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. 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 medicinal product for marketing in Ireland.

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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 Health Products Regulatory Authority (HPRA) has established the National Rules Scheme for Homeopathic Medicinal Products.

The Public Assessment Report reflects the scientific conclusion reached by the 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 Pollenna, containing the active substance(s): Allium cepa, Euphrasia officinalis and Schoenocaulon officinale (Sabadilla) all in the 6C potency.

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.

Name of the product: Pollenna 6C tablets
Name(s) of the active substance(s) Allium cepa Euphrasia officinalis Schoenocaulon officinale
Pharmaceutical form and potency(ies) Tablets 6C
Marketing Authorisation Number(s) in Ireland (HOA) 1149/006/001
Marketing Authorisation Holder
A Nelson & Company Limited

II. QUALITY ASPECTS

This application is for Pollenna tablets. The active ingredient(s) of Pollenna are derived from Allium cepa, Euphrasia officinalis and Schoenocaulon officinale plants.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Allium cepa 6C
Euphrasia officinalis 6C
Schoenocaulon officinale 6C

Excipient(s) with known effects:
Lactose 174.26 mg
Sucrose 42.39 mg

II.1 S.1 Homeopathic raw material

The homeopathic raw material specification for Allium cepa, Euphrasia officinalis and Schoenocaulon officinale are considered adequate to control the quality and meet current pharmacopoeial requirements. Batch analytical data demonstrating compliance with these specification has been provided.

II.2 S.2 Homeopathic stock

The homeopathic stocks: Allium cepa, Euphrasia officinalis and Schoenocaulon officinale are all described in an Official pharmacopoeia of a Member State - Germany, the German Homeopathic Pharmacopoeia (GHP) and are all manufactured in accordance with the principles of good manufacturing practice (GMP).

The homeopathic stock specifications are considered adequate to control the quality and meet current pharmacopoeial requirements. Batch analytical data demonstrating compliance with these specification has been provided.

II.3 Medicinal product

P.1 Composition

Pollenna consists of circular white tablets.

Composition of the medicinal product.
Allium cepa 6C
Euphrasia officinalis 6C
Schoenocaulon officinale 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.

The manufacturing process has been validated according to relevant European/ICH guidelines and the process is considered to be sufficiently validated.

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

All ingredients comply with Ph. Eur. or are adequately controlled by the manufacturer's specifications.

Adventitious agent safety

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

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

Adventitious viruses
See above

P.5 Control of finished product

The Finished Product Specification is based on the pharmacopoeial monograph for oral 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, where relevant.

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 tablets in Aluminium/PVC blister strips, packed in a cardboard carton, pack size 72 tablets.

Evidence has been provided that the packaging complies with 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 at '*not above 25^{o}C*', and '*in the original packaging in order to protect from moisture*', 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 Pollenna tablets.

III. NON-CLINICAL ASPECTS

Pollenna 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. Pollenna tablets conform to subparagraph 11.3 of the regulations and therefore are deemed appropriate for the proposed use.

There are no safety issues with this product and bibliographic evidence as well as an Expert Report has been provided to support '*homeopathic use*' as required by the Directive 2001/83/EC, as amended.
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

This is a national application submitted by A Nelson and Co Limited, under Article 16.2 of Directive 2001/83/EC, as amended.

Pollenna is a homeopathic medicinal product used for: A Homeopathic Medicinal product used within the homeopathic tradition for the symptomatic relief of hay fever and other symptoms of allergic rhinitis, such as sneezing, itchy eyes, blocked or runny nose.

IV.1 Clinical efficacy

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 Pollenna as a homeopathic medicine and not upon data generated from clinical trials.

Article 16 of 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 Pollenna tablets: *A Homeopathic Medicinal product used within the homeopathic tradition for the symptomatic relief of hay fever and other symptoms of allergic rhinitis, such as sneezing, itchy eyes, blocked or runny nose*, is in line with homeopathic indications recorded 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 symptoms worsen, or if symptoms do not improve after 7 days, consult your doctor or qualified healthcare practitioner*, will be present on the packaging.

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

Contraindications

Hypersensitivity to any of the active ingredients or any of the excipients.

Special warnings and precautions for use

Do not exceed the stated dose.

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

If symptoms worsen, or if symptoms do not improve after 7 days, a doctor or qualified healthcare practitioner should be consulted.

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 Pollenna is manufactured by Nelsons using the Pharmacopoeial (GHP) active ingredients: Allium cepa, Euphrasia officinalis and Schoenocaulon officinale 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 Pollenna tablets.
The product Pollenna tablets contains the active ingredients: Allium cepa, Euphrasia officinalis and Schoenocaulon officinale, which are controlled by monographs in the GHP. The actives are highly diluted to 6C in the finished product and adhere to the

legislation with respect to safety requirements. All excipients in Pollenna 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.
The product Pollenna has been proposed as a treatment for hayfever*: A Homeopathic Medicinal product used within the homeopathic tradition for the symptomatic relief of hay fever and other symptoms of allergic rhinitis, such as sneezing, itchy eyes, blocked or runny nose*.

Homeopathic literature and provings support the use of the active ingredients: Allium cepa, Euphrasia officinalis and Schoenocaulon officinale, for this indication. Since hayfever is considered to be a mild self-limiting condition it is 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 Pollenna 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 Pollenna is granted.