HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Assessment Report for a **Homeopathic Medicinal Product for Human Use**

Pollinosan Hayfever Tablets

HOA2309/001/001
HOA holder: A. Vogal Ireland Limited

Date 31/05/2019

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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 Pollinosan Hayfever Tablets containing Ammi visnaga 1x, Aralia racemosa 2x, Cardiospermum halicacabum 2x, Galphimia glauca 3x, Larrea mexicana 2x, Luffa operculata 6x and Okoubaka aubrevillei 2x.

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.

QUALITY ASPECTS

This application is for Pollinosan Hayfever Tablets. The active ingredients of Pollinosan Hayfever Tablets are derived from the following plants: Ammi visnaga, Aralia racemosa, Cardiospermum halicacabum, Galphimia glauca, Larrea mexicana, Luffa operculata and Okoubaka aubrevillei.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet (250mg) contains:

Ammi visnaga 1x
Aralia racemosa 2x
Cardiospermum halicacabum 2x
Galphimia glauca 3x
Larrea mexicana 2x

Luffa operculata 6x
Okoubaka aubrevillei 2x

(Full composition P1 below)

II.1 S.1 Homeopathic raw material

The homeopathic raw materials specifications for Ammi visnaga, Aralia racemosa, Cardiospermum halicacabum, Galphimia glauca, Larrea mexicana, Luffa operculata and Okoubaka aubrevillei are considered adequate to control the quality and meet current pharmacopoeial requirements. Batch analytical data demonstrating compliance with these specifications have been provided.

II.2 S.2 Homeopathic stock

The homeopathic stocks: Ammi visnaga, Aralia racemosa, Cardiospermum halicacabum, Galphimia glauca, Larrea mexicana, Luffa operculata and Okoubaka aubrevillei, all have official monographs in an Official pharmacopoeia of a Member State, the German Homeopathic Pharmacopoeia, (GHP) or in the Homeopathic Pharmacopoeia of the United States (HPUS) and are manufactured in accordance with the principles of good manufacturing practice (GMP).

The homeopathic stocks 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

Tablet.
Yellowish, biconvex tablet with a triangular stamp.

Composition of the medicinal product.

Ammi visnaga 1x
Aralia racemosa 2x
Cardiospermum halicacabum 2x
Galphimia glauca 3x
Larrea mexicana 2x
Luffa operculata 6x
Okoubaka aubrevillei 2x

Lactose monohydrate

Pregelatinised starch
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

Pollinosan Hayfever Tablets does not contain ingredients of human or animal origin except for lactose obtained from milk from animals fit for human consumption, therefore there is no risk from these agents in respect of this product.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for 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, where appropriate, 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 finished product is packed into Amber glass bottles and closed with pilfer proof screw caps. All containers and packaging comply with appropriate standards as required.

Pack sizes: 80 tablets

120 tablets

Evidence has been provided that the container 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 has been provided in accordance with EU guidelines demonstrating the stability of the product for 5 years.

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 Pollinosan Hayfever Tablets.

NON-CLINICAL ASPECTS

The product Pollinosan Hayfever Tablets is a homeopathic medicinal product as defined by Directive 2001/83/EC, as amended.

Preclinical studies have been submitted along with an Expert Report. These were acceptable for this type of application according to the regulations. The product Pollinosan Hayfever Tablets conforms to subparagraph 11.3 of the regulations (Statutory Instrument 540 of 2007) and therefore is deemed appropriate for the proposed use.

There are no safety issues with this product and bibliographic evidence 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 dilute active ingredients and therefore pose no environmental risk.

CLINICAL ASPECTS

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

Pollinosan Hayfever Tablets is a homeopathic medicinal product used for: *A homoeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of hayfever and other forms of allergic rhinitis.*

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 Pollinosan Hayfever Tablets 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 Pollinosan Hayfever Tablets: A homoeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of hayfever and other forms of allergic rhinitis*, 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 the relevant information.

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 *'See your doctor If your symptoms worsen, or do not improve after 7 days,* is present on the packaging.

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

Contraindications

Hypersensitivity to any of the active substances or to any of the excipients listed in 6.1

Special warnings and precautions for use

Do not exceed the stated dose.

If the condition worsens or if symptoms persist for more than 7 days, a qualified

healthcare professional e.g. a doctor or pharmacist should be consulted.

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

This product is not recommended for use in children under 12 years of age due to a lack of data on safety.

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 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.

OVERALL CONCLUSIONS

The product Pollinosan Hayfever Tablets is manufactured by Bioforce AG for the HOA holder: A. Vogal Ireland Limited using the Pharmacopoeial (GHP/HPUS) active ingredients, Ammi visnaga, Aralia racemosa, Cardiospermum halicacabum, Galphimia glauca, Larrea mexicana, Luffa operculata and Okoubaka aubrevillei and excipients according to Ph. Eur. Manufacturing processes are well described and controlled and appropriate for this type of oral tablet 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 Pollinosan Hayfever Tablets.

The product Pollinosan Hayfever Tablets contains the active ingredients, Ammi visnaga, Aralia racemosa, Cardiospermum halicacabum, Galphimia glauca, Larrea mexicana, Luffa operculata and Okoubaka aubrevillei and are controlled by monographs in the GHP/HPUS. The actives are diluted in the finished product and adhere to the legislation with respect to safety requirements. All excipients in Pollinosan Hayfever Tablets 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 Pollinosan Hayfever Tablets has been proposed as a treatment for Hayfever: *A homoeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of hayfever and other forms of allergic rhinitis*.

Homeopathic literature and provings support the use of the active ingredients: Ammi visnaga, Aralia racemosa, Cardiospermum halicacabum, Galphimia glauca, Larrea mexicana, Luffa operculata and Okoubaka aubrevillei, 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 Pollinosan Hayfever 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 National Rules Authorisation for Pollinosan Hayfever Tablets is granted.

DATE OF APPROVAL

<Insert date>

REVISION DATE

<Insert date>

UPDATES

<Insert updates>