Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pollinosan Hayfever tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet (250 mg) contains:

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

Excipients with known effect:
Contains lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Slightly yellowish, biconvex tablet with a triangular stamp.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A homoeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of hayfever and other forms of allergic rhinitis.
This product is indicated for use in adults and adolescents over 12 years.

4.2 Posology and method of administration

Posology
Adults, older people and adolescents over 12 years: Take 2 tablets 3 times daily before meals.
Maximum recommended daily dose is 6 tablets.
This product should not be used in children under 12 years.
Method of administration
For oral use only.

4.3 Contraindications

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

4.4 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.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

There is no evidence on the safety of this product in human pregnancy, nor is there any evidence from animal studies. The use of this product during pregnancy and lactation should be avoided unless under the guidance of a doctor. Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

Pollinosan has no influence on the ability to drive or use machines.

4.8 Undesirable effects

Frequency not known
Gastrointestinal disturbances e.g. nausea, stomach upset.
Allergic reactions e.g. rash
If symptoms worsen, or persist for more than 7 days, or if other adverse reactions not mentioned above occur, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

None known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Pregelatinised starch
Magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottles (Type III glass) sealed with coated aluminium foil and closed with pilfer proof screw caps fitted with a polyethylene liner
Pack sizes: 80 tablets, 120 tablets
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

A.Vogel Ireland Limited
Unit 3d
Killeen Road
Dublin 10
D10 TY20
Ireland

8 MARKETING AUTHORISATION NUMBER

HOA2309/001/001

8 REGISTRATION NUMBER(S)

HOA2309/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st May 2019

10 DATE OF REVISION OF THE TEXT

September 2019