# Helios Hay Fever 30c Pillules

**NR 27776/0006**

**UKPAR**

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HELIOS HAY FEVER 30C PILLULES

NR 27776/0006

LAY SUMMARY

The Medicines and Healthcare Products Regulatory Agency (MHRA) granted Helios Homeopathy Limited a Homeopathic Marketing Authorisation for the homeopathic medicinal product Helios Hay Fever 30c Pillules (Homeopathic Marketing Authorisation number: NR 27776/0006) on 16 January 2014. This product is available without prescription and can be bought from pharmacies and other outlets.

Helios Hay Fever 30c Pillules is a homeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of hay fever. This indication is based on published Materia medica references. The active ingredients are *Allium cepa* 30c, *Euphrasia officinalis* 30c and *Schoenocaulon officinale* 30c.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Homeopathic Marketing Authorisation could be granted.
HELIOS HAY FEVER 30C PILLULES

NR 27776/0006

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Homeopathic Marketing Authorisation for the homeopathic medicinal product Helios Hay Fever 30c Pillules on 16 January 2014. This product is on the General Sales List (GSL).

The application was submitted in accordance with Article 16.2 of Directive 2001/83 EC, as amended, under the National Rules Authorisation Scheme. Helios Hay Fever 30c Pillules contain the homeopathic stocks *Allium cepa* 30c, *Euphrasia officinalis* 30c and *Schoenocaulon officinale* 30c. It is used to relieve the symptoms of hay fever.

*Allium cepa*, *Euphrasia officinalis* and *Schoenocaulon officinale* are established homeopathic remedies and their traditional use in homoeopathy is well documented. In support of this application to authorise Helios Hay Fever 30c Pillules details of published homeopathic *Materia medica* references for the individual stocks within the product have been provided.
PHARMACEUTICAL ASSESSMENT

RAW MATERIAL
(HERBAL SUBSTANCE):  ALLIUM CEPA

Scientific name:  Allium cepa L.
Plant family:  Amaryllidaceae

Manufacture
The Allium cepa plants are cultivated in Switzerland. The plant is harvested by hand when ripe.

Satisfactory details of the pesticides, fertilisers, herbicides and fungicides used for cultivation are provided. Confirmation has been provided that the herbal substance is produced in line with the Guideline on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin (EMEA/HMPC/246816/2005).

Control of the Herbal Substance
The Allium cepa is described in the German Homeopathic Pharmacopoeia (GHP) and its quality is satisfactorily controlled.

Satisfactory Certificates of Analysis are provided.

Container Closure System
No details are required.

Stability
A shelf-life for the herbal substance is not necessary because it is collected and used in the fresh state.

ACTIVE INGREDIENT
(HOMEOPATHIC STOCK):  ALLIUM CEPA 30C
Extraction solvent:  Ethanol 86 % (m/m)
General properties:  A light yellow to reddish yellow liquid with a strong onion-like odour and taste

Manufacture
A satisfactory description of the manufacturing process of the homeopathic stock has been provided. Allium cepa mother tincture is manufactured according to method 2a of the Ph. Eur. The in-process controls are satisfactorily detailed. Certificates of Analysis for all materials used in the manufacture of the homeopathic stock have been provided.

Control of Homeopathic Stock
A satisfactory specification with appropriate tests and limits has been provided for the homeopathic stock. Analytical methods have been validated, as appropriate.
Satisfactory Certificates of Analysis are provided for batches of the homeopathic stock, demonstrating satisfactory compliance with the proposed specifications.

**Container Closure System**
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to materials and articles intended to come into contact with foodstuffs.

**Stability**
A shelf-life for the herbal substance is not necessary because it is collected and used in the fresh state.

### RAW MATERIAL
**(HERBAL SUBSTANCE):** *Euphrasia officinalis*

**Scientific name:** *Euphrasia officinalis* L.  
**Plant family:** Orobanchaceae

**Manufacture**
The *Euphrasia officinalis* plants are hand collected from the wild in Switzerland. The plants are hand collected during flowering.

Confirmation has been provided that pesticides and fertilisers are not used and that the herbal substance is produced in line with the Guideline on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin (EMEA/HMPC/246816/2005).

**Control of the Herbal Substance**
The raw material is described in the GHP and the applicant refers to the test specifications mentioned therein. As *Euphrasia officinalis* is described in an official pharmacopoeia, the analytical tests do not require further validation.

Satisfactory Certificates of Analysis are provided.

**Container Closure System**
No details are required.

**Stability**
A shelf-life for the herbal substance is not necessary because it is collected and used in the fresh state.

### ACTIVE INGREDIENT
**(HOMEOPATHIC STOCK):** *Euphrasia officinalis* 30C

**Extraction solvent:** Ethanol 86 % (m/m)  
**General properties:** A dark brown liquid with an herby odour and taste

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MHRA PAR; HELIOS HAY FEVER 30C PILLULES, NR 27776/0006
Manufacture
A satisfactory description of the manufacturing process of the homeopathic stock has been provided. *Euphrasia officinalis* mother tincture is manufactured according to method 3c of the Ph. Eur. The in-process controls are satisfactorily detailed. Certificates of Analysis for all materials used in the manufacture of the homeopathic stock have been provided.

Control of Homeopathic Stock
A satisfactory specification with appropriate tests and limits has been provided for the homeopathic stock. Analytical methods have been validated, as appropriate.

Satisfactory Certificates of Analysis are provided for batches of the homeopathic stock, demonstrating satisfactory compliance with the proposed specifications.

Container Closure System
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to materials and articles intended to come into contact with foodstuffs.

Stability
Confirmation has been provided that the homeopathic stock will be tested in accordance with the GHP monograph prior to the manufacture of each batch of the finished product. This is acceptable.

RAW MATERIAL
(HERBAL SUBSTANCE): *SCHOENOCAULON OFFICINALE*
Scientific name: *Schoenocaulon officinale* Cham. et Schlechtend
Plant family: Melanthiaceae

Manufacture
The *Schoenocaulon officinale* plants are hand collected from the wild in Venezuela. The plants are collected from October-December.

Confirmation has been provided that pesticides and fertilisers are not used and that the herbal substance is produced in line with the Guideline on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin (EMEA/HMPC/246816/2005).

Control of the Herbal Substance
The *Schoenocaulon officinale* is described in the GHP and its quality is satisfactorily controlled.

Satisfactory Certificates of Analysis are provided.

Container Closure System
No details are required.

Stability
Stability data are not required.

**ACTIVE INGREDIENT**
**(HOMEOPATHIC STOCK):**  
**SCHOENOCAULON OFFICINALE 30C**

**Extraction solvent:**  
Ethanol 86 % (m/m)

**General properties:**  
A dark reddish brown liquid with no particular odour

**Manufacture**
A satisfactory description of the manufacturing process of the homeopathic stock has been provided. *Schoenocaulon officinale* mother tincture is manufactured according to method 4a of the Ph. Eur. The in-process controls are satisfactorily detailed. Certificates of Analysis for all materials used in the manufacture of the homeopathic stock have been provided.

**Control of Homeopathic Stock**
A satisfactory specification with appropriate tests and limits has been provided for the homeopathic stock. Analytical methods have been validated, as appropriate.

Satisfactory Certificates of Analysis are provided for batches of the homeopathic stock, demonstrating satisfactory compliance with the proposed specifications.

**Container Closure System**
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to materials and articles intended to come into contact with foodstuffs.

**Stability**
Confirmation has been provided that the homeopathic stock will be tested in accordance with the GHP monograph prior to the manufacture of each batch of the finished product. This is acceptable.

**HOMEOPATHIC MEDICINAL PRODUCT: HELIOS HAY FEVER 30C PILLULES**

**Description and Composition of the Homeopathic Product**
The finished product is a white, hard, roughly spherical pillule containing *Allium cepa* 30c, *Euphrasia officinalis* 30c and *Schoenocaulon officinale* 30c and the pharmaceutical excipient sucrose. This excipient is considered to be compatible with the homeopathic stocks.

The excipient used complies with the Ph. Eur. monograph.

**Manufacture of the Homeopathic Product**
A flow diagram outlining the various stages of the manufacturing process and the in-process controls is provided.
The critical steps of the process have been validated satisfactorily.

**Control of the Homeopathic Product**
The finished product specification is detailed and the tests and limits used were found to be satisfactory for a product of this nature.

Satisfactory details have been provided on all analytical procedures and these analytical procedures are acceptable.

**Container Closure System**
The product is presented in a 4g round plastic tubular dispenser consisting of a polypropylene body, polypropylene dispensing head and polystyrene cap. The main polypropylene body contains an inner polystyrene tube.

Each container contains approximately 100 pillules. The components of the primary packaging system comply with current legislation relating to materials and articles intended to come into contact with foodstuffs.

**Stability of the Homeopathic Product**
Stability studies were conducted under ICH conditions on product batches in the container type proposed for marketing. The results of the stability studies support the 5 year shelf-life for the product when the storage precaution ‘Store below 30°C away from direct sunlight’ is applied.

**Summary of Product Characteristics, Labels and Patient Information Leaflet**
The product literature for this product is pharmaceutically satisfactory.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

**CONCLUSION**
There are no objections to the granting of a Homeopathic Marketing Authorisation from a quality point of view.
NON-CLINICAL AND CLINICAL SAFETY ASSESSMENT

The safety data which must be submitted by the Applicant is set out in Schedule 1A – Part 1 and Part 2 of Statutory Instrument 2006 No.1952 The Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006. Point 4 of Part 2 states the conditions under which the Applicant is not required to provide any data on the safety of the product. In such cases one of the following must apply:

a. The product is intended to be administered orally and is derived from a stock which is commonly present in food.
b. The product is derived from a stock present in a licensed medicinal product (i.e. product has a marketing authorisation, certificate of registration, herbal registration or product licence) and that the product is available via general sales, provided the product has the same degree of dilution and route of administration as the licensed product.
c. The product is derived from a stock diluted to at least $10^{24}$ and is not a material of biological origin.

The homeopathic stocks are diluted to at least $10^{24}$ and are not materials of biological origin, therefore, criteria c is fulfilled. No further information is required on the safety of the individual stocks.

All of the stocks are diluted to 30c ($10^{60}$) and there are no issues regarding the safety of the combination of stocks in the finished product.

Helios Hay Fever 30c Pillules contain sucrose. Warnings have been included in the SmPC, patient information leaflet and labels accordingly.

CONCLUSION

There are no objections to the granting of a Homeopathic Marketing Authorisation from a safety point of view.
CLINICAL ASSESSMENT

LEGAL STATUS
General sales list (GSL) status has been applied for and is applicable for the dilutions of *Allium cepa*, *Euphrasia officinalis* and *Schoenocaulon officinale* to be authorised.

INDICATION
The applicant has proposed the following indication:

“A homeopathic medicinal product used within the homeopathic tradition to relieve the symptoms of hay fever.”

This indication is acceptable.

EVIDENCE SUPPORTING THE PROPOSED INDICATION
Schedule 1A Parts 1 and 3 of SI 2006 No. 1952 The Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006 specifies the data that must be provided to support the use of the product in the indications sought.

The applicant must provide one of the following: published scientific literature, homeopathic provings and/or study reports in relation to the product which is the subject of the application. An evaluation of the data must be provided, including an explanation as to how the data establishes that the product to be authorised has a recognised level of efficacy in the indications sought. The data provided must be sufficient to demonstrate that UK homeopathic practitioners would accept the usage of the product within the homeopathic tradition for the indications sought.

The applicant has provided published homeopathic *Materia medica* references for the individual stocks to support their use in Helios Hay Fever 30c Pillules for the indications sought and has provided a justification for the combination of stocks in the product to be authorised. Statements from UK homeopathic practitioners have been provided to further support the use of the product for the indications sought within the UK homeopathic tradition.

It is considered sufficient evidence has been submitted to support the use Helios Hay Fever 30c Pillules within the homeopathic tradition to relieve the symptoms of hay fever

CONCLUSION
There are no objections to the granting of a Homeopathic Marketing Authorisation from a clinical point of view.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

CLINICAL
The applicant has provided literature references as supporting evidence to fulfil the requirements for this type of application. These relate to the indications sought and are, therefore, acceptable.

PRODUCT LITERATURE
The SmPC, PIL and labels for the product are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified.
### STEPS TAKEN FOR ASSESSMENT

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<td>The MHRA received an application under the Homeopathic National Rules Scheme (Article 16.2) on 3 June 2011</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 4 November 2011</td>
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<td>3</td>
<td>Following assessment of the application and a meeting of the Advisory Board on the Registration of Homeopathic products (ABRH) on 11 December 2012, the MHRA requested further information relating to the dossier on 8 April 2013, 14 August 2013 and 8 November 2013</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on the dossier on 21 June 2013, 4 October 2013 and 12 November 2013</td>
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<td>5</td>
<td>A National Rules Marketing Authorisation was granted on 16 January 2014</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
LABELLING

Label:

Turn upside-down and twist lid slowly to dispense one pillule

HOMEOPATHIC MEDICINAL PRODUCT

HELIOS HAY FEVER

30c Pillules Each pillule contains:
Allium cepa 30c, Euphrasia officinalis 30c
Schoenocaulon officinale (Sabadilla), 30c

ADULTS, THE ELDERLY AND CHILDREN AGED 2 YEARS
and above: One pillule to be sucked as required up to 3

times daily.

Not recommended for children under 2 years:
For younger children and those unable to suck the pillule, it
may be crushed or dissolved in

half a teaspoonful of previously boiled, cooled
water and then administered.

Do not exceed the stated dose.
See leaflet for further information.
Keep out of the reach and sight of children.

HELIOS HOMEOPATHY LTD

NR27776/0006 4g pillules/(100 approx)