Helios Stress Relief 30c Pillules

NR 27776/0004

UKPAR

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Helios Homeopathy Limited a Homeopathic Marketing Authorisation for the homeopathic medicinal product Helios Stress Relief 30c Pillules (Homeopathic Marketing Authorisation number: NR 27776/0004) on 6 August 2013. This product is available without prescription and can be bought from pharmacies and other outlets.

Helios Stress Relief 30c Pillules is a homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of symptoms associated with mild stress. This indication is based on published homeopathic provings. The active ingredients in Helios Stress Relief 30c Pillules are *Aconitum napellus* 30c, *Argentum nitricum* 30c and *Arsenii trioxidum* 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 STRESS RELIEF 30C PILLULES

NR 27776/0004

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Homeopathic Marketing Authorisation for the homeopathic medicinal product Helios Stress Relief 30c Pillules on 6 August 2013. 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 Stress Relief 30c Pillules contain the homeopathic stocks *Aconitum napellus* 30c, *Argentum nitricum* 30c and *Arsenii trioxidum* 30c. The pillules are used for the symptomatic relief of symptoms associated with mild stress.

*Aconitum napellus, Argentum nitricum* and *Arsenii trioxidum* are established homeopathic remedies and their traditional use in homeopathy is well documented. In support of this application to authorise Helios Stress Relief 30c Pillules details of published homeopathic *Materia medica* provings of the individual stocks within the product has been provided.
PHARMACEUTICAL ASSESSMENT

RAW MATERIAL:  ARGENTUM NITRICUM
Scientific name:  Silver nitrate
Chemical formula:  AgNO₃.

Manufacture
The raw material is purchased from a well-established chemical supplier.

Control of the stock
The applicant refers to the German Homeopathic Pharmacopoeia (GHP) monograph which refers to the Ph. Eur. for silver nitrate and is, therefore, satisfactory.

A satisfactory Certificate of Analysis is provided.

Container Closure System
Satisfactory details of the container closure system used to store the raw material are provided.

Stability
Stability data are not required as the raw material is tested against the Ph. Eur. monograph immediately prior to the manufacture and release of each batch. This is satisfactory.

ACTIVE INGREDIENT
(HOMEOPATHIC STOCK):  ARGENTUM NITRICUM (D1 SOLUTION)
Extraction solvent:  Purified water
General properties:  A clear, colourless liquid

Manufacture
A satisfactory description of the manufacturing process of the homeopathic stock has been provided. The D1 solution is prepared according to method 5a 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.

Appropriate analytical procedures are used to control the quality of the homeopathic stock. As the analytical methods are in accordance with the GHP monograph additional validation is not required.

A satisfactory Certificate of Analysis is provided for a batch 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 plastic materials and articles intended to come into contact with foodstuffs.

**Stability**
Satisfactory stability data are provided.

**RAW MATERIAL**
(HERBAL SUBSTANCE):  **ACONITUM NAPELLUS (ACONITE)**

- **Scientific name:** Aconite napellus L
- **Plant family:** Ranunculaceae

** Manufacture**
The *Aconite napellus* plants are collected from the wild in Switzerland. Fresh whole plants are hand collected at the start of flowering and then washed (if necessary) and minced.

Confirmation has been provided that pesticides 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 *Aconite napellus* is described in an official pharmacopoeia, the analytical tests do not require further validation.

A satisfactory Certificate of Analysis is provided.

**Container Closure System**
Satisfactory details of the container closure system used to store the herbal substance are provided.

**Stability**
Stability data are not required as the herbal substance is tested according to the monograph for the herbal drug in the GHP immediately prior to tincture manufacture and the material is used fresh.

**ACTIVE INGREDIENT**
(HOMEOPATHIC STOCK):  **ACONITUM NAPELLUS MOTHER TINCTURE**

- **Extraction solvent:** Ethanol 86 % (m/m)
- **General properties:** A greenish yellow, later turning brownish yellow, liquid with a characteristic odour

** Manufacture**
A satisfactory description of the manufacturing process of the homeopathic stock has been provided. *Aconite napellus* mother tincture is manufactured according to method 2a of the GHP. 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.
appropriate analytical procedures are used to control the quality of the homeopathic stock. As the analytical methods are in accordance with the GHP monograph additional validation is not required.

A satisfactory Certificate of Analysis is provided for a batch 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 plastic 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: ARSENIUM TRIOXIDUM (ARSENICUM ALBUM)
Scientific name: Arsenious trioxide
Chemical formula: As₂O₃

Manufacture
The raw material is purchased from a well-established chemical supplier.

Control of the Herbal Substance
The applicant refers to the GHP monograph which refers to the Ph. Eur. for Arsenious trioxide and is, therefore, satisfactory.

A satisfactory Certificate of Analysis is provided.

Container Closure System
Satisfactory details of the container closure system used to store the raw material are provided.

Stability
Stability data are not required as the raw material is tested against the Ph. Eur. monograph prior to the manufacture and release of each batch. This is satisfactory.

ACTIVE INGREDIENT
(HOMEOPATHIC STOCK): ARSENIUM TRIOXIDUM (D1 TRITURATION)
Diluent: Lactose
General properties: A white powder

Manufacture
A satisfactory description of the manufacturing process of the homeopathic stock has been provided. The D1 trituration is prepared according to method 6 of the GHP. 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.

Appropriate analytical procedures are used to control the quality of the homeopathic stock. As the analytical methods are in accordance with the GHP monograph additional validation is not required.

A satisfactory Certificate of Analysis is provided for a batch 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 plastic materials and articles intended to come into contact with foodstuffs.

**Stability**
Satisfactory stability data are provided.

**HOMEOPATHIC MEDICINAL PRODUCT: HELIOS STRESS RELIEF 30C PILLULES**

**Description and Composition of the Homeopathic Product**
The finished product is a white, hard, roughly spherical pillule, approximately 4 mm in diameter. The pillules contain *Aconitum napellus* in a final dilution of 30c, *Argentum nitricum* in a final dilution of 30c and *Arsenii trioxidum* in a final dilution of 30c and the excipient sucrose. The sucrose complies with the Ph. Eur. monograph and is considered to be compatible with the homeopathic stocks. Certificates of Analysis for the sucrose have been provided by the supplier.

**Manufacture**
A description of the various stages of the manufacturing process and the in-process controls is provided.

The critical steps of the process have been validated and a report on process validation/evaluation has been provided; the production process is considered validated.

**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 valid.
Certificates of Analysis have been presented for batches of the drug product demonstrating little inter-batch variation.

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

**Stability**
Stability studies were conducted under ICH conditions on product batches in the container type proposed for marketing.

This product has a shelf life of 5 years, which is appropriate when the storage precautions “Store below 30ºC away from direct sunlight and strong odours” and “Store in the original package” are 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.

Aconitum napellus and Arsenii trioxidum have been registered under the Simplified Homeopathic Registration scheme as homeopathic single stock remedies, are diluted to at least $10^{-24}$ and are not materials of biological origin, therefore, criteria b and c are fulfilled. Argentum nitricum is diluted to at least $10^{-24}$ and is not a material 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 Stress Relief 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.
LEGAL STATUS
The Applicant has proposed that Helios Stress Relief 30c Pillules is classified as a General Sales List (GSL) product. Aconitum napellus and Arsenii trioxidum are included on the Prescription Only Medicines (POM) Order at dilutions up to 6X, meaning that dilutions from 6X are exempt from POM control and are classified as GSL. Argentum nitricum is listed on the GSL Order. Therefore, it is considered that Helios Stress Relief 30c Pillules is suitable for General Sales.

INDICATION
The applicant has proposed the following indication:

“A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of symptoms associated with mild stress.”

This indication is acceptable.

POSOLOGY AND METHOD OF ADMINISTRATION
The applicant has proposed the following

“For oral use.

Adults and the elderly:
One pillule to be sucked as required up to 3 times daily

The pillule maybe crushed or dissolved in half a teaspoonful of previously boiled, cooled water.

Paediatric population:
This product is not recommended for children or adolescents under 18 years of age.

If symptoms worsen or do not improve after taking the product for 4 days, a doctor or qualified health care practitioner should be consulted.

Do not take within 15 minutes of eating or drinking.”

This 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 has provided references in the form of published homeopathic Materia medica provings of the individual stocks within the product to support the use of the individual stocks in Helios Stress Relief 30c Pillules in 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 of Helios Stress Relief 30c Pillules within the homeopathic tradition for the symptomatic relief of symptoms associated with mild stress.

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.

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

The SmPC, PIL and labelling of 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.
HELIOS STRESS RELIEF 30C PILLULES

NR 27776/0004

STEPS TAKEN FOR ASSESSMENT

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<tr>
<td>1</td>
<td>The MHRA received an application under the Homeopathic National Rules Scheme (Article 16.2) on 22 February 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 17 May 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 18 October 2011, the MHRA requested further information relating to the dossier on 31 October 2011</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s request, providing further information on the dossier on 26 April 2013</td>
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<td>5</td>
<td>A National Rules Marketing Authorisation was granted on 6 August 2013</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Helios Stress Relief 30c Pillules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each pillule contains
Aconitum napellus (Aconite) 30c
Argentum nitricum (Argent. Nit.) 30c
Arsenii trioxidum (Arsenicum album/Arsen. Alb) 30c

Each pillule contains sucrose 40mg (See Section 4.4. ‘Special warnings and precautions for use.’)
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Pillules
White, hard, roughly spherical, approximately 4mm in diameter.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of symptoms associated with mild stress.

4.2 Posology and method of administration
For oral use.

Adults and the elderly:
One pillule to be sucked as required up to 3 times daily

The pillule maybe crushed or dissolved in half a teaspoonful of previously boiled, cooled water.

Paediatric population:
This product is not recommended for children or adolescents under 18 years of age.

If symptoms worsen or do not improve after taking the product for 4 days, a doctor or qualified health care practitioner should be consulted.

Do not take within 15 minutes of eating or drinking.
4.3 **Contraindications**
Hypersensitivity to Aconitum napellus (Aconite), Argentum nitricum (Argent. Nit) or Arsenii trioxidum (Arsenicum album/Arsen. Alb) preparations or to any of the excipients.

4.4 **Special warnings and precautions for use**
Contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose/galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

If symptoms worsen or do not improve within 4 days, a doctor or qualified health care practitioner should be consulted.

This product is not recommended for children or adolescents under 18 years of age.

This product is intended for the relief of symptoms associated with mild stress.

Patients with signs and symptoms of depression should seek medical advice for appropriate treatment.

Do not exceed the stated dose.

4.5 **Interaction with other medicinal products and other forms of interaction**
None known.

4.6 **Fertility, pregnancy and lactation**
Pregnancy: There is no evidence of the safety of the product in human pregnancy, nor is there any evidence from animal studies.

Lactation: There is no evidence to suggest that the product should not be used during lactation.

Although no adverse events have been observed, the use of this product during pregnancy and lactation should be avoided unless under the guidance of a doctor.

Studies on fertility have not been performed.

4.7 **Effects on ability to drive and use machines**
None known.

4.8 **Undesirable effects**
There are no known adverse effects.

If adverse effects occur, a doctor or qualified health care practitioner 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 of the medicinal product. Healthcare professionals are asked to report any suspected
adverse reactions via the Yellow card Scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose
None known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic Group
The ATC code is V03. All other therapeutic groups.

5.2 Pharmacokinetic properties
Not applicable

5.3 Preclinical safety data
Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Suucrose

6.2 Incompatibilities
None known

6.3 Shelf life
5 years

6.4 Special precautions for storage
Store below 30ºC away from direct sunlight and strong odours.
Store in the original package.

6.5 Nature and contents of container
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.

Pack size: 4g Pillules (100 approx)

6.6 Special precautions for disposal
There are no special precautions.

7 MARKETING AUTHORISATION HOLDER
Helios Homeopathy Limited
89-97 Camden Road
Tunbridge Wells
Kent
TN1 2QR
U.K.
Tel 01892 537 254
Fax 01892 546850
Email johnm@helios.co.uk

8 MARKETING AUTHORISATION NUMBER(S)
NR 27776/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
06/08/2013

10 DATE OF REVISION OF THE TEXT
06/08/2013
PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER
HOMEOPATHIC MEDICINAL PRODUCT

Name of medicine: Helios Stress Relief 30c Pillules
Aconite napellus (Aconite) 30c, Argentum nitricum (Argent. Nit.) 30c, Arsenii trioxidum (Arsenicum album/Arsen. Alb 30c.)

Read all of this leaflet carefully because it contains important information for you.
This medicinal product is available without prescription. However, you still need to take Helios Stress Relief 30c Pillules carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your Pharmacist or qualified healthcare practitioner if you need more information or advice.
- If the condition worsens, or if symptoms persist for more than 4 days, or if unexpected or unwanted effects occur, consult a doctor or qualified healthcare practitioner.

In this leaflet
1. What Helios Stress Relief 30c Pillules is and what it is used for
2. Before you take Helios Stress Relief 30c Pillules
3. How to take Helios Stress Relief 30c Pillules
4. Possible side effects
5. How to store Helios Stress Relief 30c Pillules
6. Further Information

1. WHAT HELIOS STRESS RELIEF 30c PILLULES IS AND WHAT IT IS USED FOR
Helios Stress Relief 30c Pillules is a homeopathic medicinal product used within the homeopathic tradition for the relief of symptoms associated with mild stress.
This product is intended for the relief of symptoms of mild stress. Patients with signs and symptoms of depression should consult their doctor for advice.

2. BEFORE YOU TAKE HELIOS STRESS RELIEF 30c PILLULES
This product contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
If you are going to see your doctor or qualified healthcare practitioner, you must tell him/her that you are taking this product.
If you are taking any other medicines including those bought without a doctor’s prescription, consult your doctor or pharmacist before taking this product.
Do not take this product if you are allergic to any of the ingredients. (see section 6) or if you are under 18 years of age.

Pregnancy and breast feeding
If you are pregnant or breast feeding, consult your doctor, qualified healthcare practitioner or pharmacist before taking this product.

3. HOW TO TAKE HELIOS STRESS RELIEF 30c PILLULES
For oral use
Turn the container upside down and twist the lid slowly to dispense one pillule into the cap. Tip the pillule into your mouth without touching it. Repeat as required for a maximum of 3 times daily.
Do not take within 15 minutes of eating or drinking.
Adults and the elderly
One pillule to be sucked as required up to 3 times daily.
The pillule maybe crushed or dissolved in half a teaspoonful of previously boiled, cooled water.

This product is not recommended for children or adolescents under 18 years of age.

Duration of treatment
Stop taking Helios Stress Relief 30c Pillules on improvement of symptoms. If your symptoms worsen or persist for more than 4 days, consult your doctor or qualified healthcare practitioner.

What to do if you take too much of this product
If you take too much of this product (overdose) and feel unwell, speak to a doctor/pharmacist and take this leaflet with you.

What to do if you miss a dose
If you forget to take this product, continue to take your usual dose at the usual time, it does not matter if you have missed a dose. Do not take a double dose to make up for a missed dose.
If you have any further questions on the use of this product, ask your doctor, qualified healthcare practitioner or pharmacist.

4. POSSIBLE SIDE EFFECTS
There are no known side effects of this product. However if you experience any unusual or unexpected effects, consult your doctor or pharmacist.

Reporting side effects
You can help to make medicines safer by reporting side effects to the yellow card scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your GP's surgery or pharmacy, or call free phone 0808 100 3352 (available 10am-2pm Monday- Friday).

5. HOW TO STORE HELIOS STRESS RELIEF 30C PILLULES
Keep out of reach and sight of children.
Do not use after the expiry date which should be stated on the container label and carton label. The expiry date refers to the last day of that month.
Store below 30°C away from direct sunlight and strong odours. Store in the original package.
If you notice the medicine showing any signs of deterioration consult your pharmacist before using this medicine.
Return any unused product to your pharmacist for safe disposal.

6. FURTHER INFORMATION
Each pillule contains:
Aconite nupellus (Aconite) 30c
Argentum nitricum (Argent. Nit.) 30c
Arsenii trioxidum (Arsenicum album/Arsen. Alb) 30c
Also contains sucrose

What Helios Stress Relief 30c pillules looks like and the contents of the pack
Each 4g pack size contains approximately 100 pillules.
The pillules are white spheres approximately of 4mm diameter.

National Rules authorisation holder and Manufacturer
LABELLING

Label:

Turn upside-down and twist lid slowly to disperse one pillule.

HOMEOPATHIC MEDICINAL PRODUCT
HELIOS STRESS RELIEF
30c Pillules

Each pillule contains: Aconite napellus (Aconite) 30c
Argentum nitricum (Argent. Nit) 30c
Arsenicum album (Arsenicum album/Arsen. alb.) 30c

ADULTS & ELDERLY: One pillule to be sucked as required up to 3 times daily.

This product is not recommended for children and adolescents under 16 years of age.
The pillule may be crushed or dissolved in half a teaspoonful of previously boiled, cooled water.

Do not exceed the stated dose.

See leaflet for further information.

Keep out of the reach and sight of children.

HELIOS HOMEOPATHY LTD

NR27776/0004 4g pillules (100 approx)
Carton: