Arnicare Arnica 30c pillules

NR 01175/0181

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ARNICARE ARNICA 30C PILLULES

NR 01175/0181

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted A. Nelson & Co. Ltd a homeopathic marketing authorisation for the homeopathic medicinal product Arnicare Arnica 30c pillules (homeopathic marketing authorisation number: NR 01175/0181). This product is available without prescription and can be bought from pharmacies and other outlets.

Arnicare Arnica 30c pillules is a homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of sprains, muscular aches and bruising and swelling after contusions. The pillules' active ingredient is Arnica montana 30c. These indications are based on:

- Published scientific literature

- Homeopathic provings (a homeopathic proving is the method by which the profile of a homeopathic remedy is determined and can be used to establish its potential applications.)

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a homeopathic marketing authorisation could be granted.

ARNICARE ARNICA 30C PILLULES

NR 01175/0181

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a homeopathic marketing authorisation for the homeopathic medicinal product Arnicare Arnica 30c pillules to A. Nelson & Co. Ltd on 24 April 2009. 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.

The homeopathic medicinal product consists of white to off-white spherical pillules for oral administration, containing 30c (GHP) Arnica montana. It is used for the symptomatic relief of sprains, muscular aches and bruising and swelling after contusions. Two pillules should be taken every 2 hours for the first six doses, then four times daily until symptoms improve for up to a maximum of 7 days.

Arnica montana is an established homeopathic remedy and its traditional use in homoeopathy is well documented. Arnica is widely available in the UK and is commonly administered in the form of a cream, gel or oral pillules. In support of this application to authorise Arnica 30c in the form of oral pillules, published scientific literature and homeopathic provings have been provided. Nelsons Arnica 30c pillules have been registered under Article 14 of Directive 2001/83 EC, as amended (the Simplified Homeopathic Registration scheme) since June 1998.

PHARMACEUTICAL ASSESSMENT

ACTIVE INGREDIENT: ARNICA MONTANA 30C

Mother Tincture of:	Arnica montana
Scientific Name:	Arnica montana L.
State and part(s) of the plant:	Whole fresh flowering
Synonyms:	Leopard's or wolf's Bane Mountain Tobacco (Engl)
Homeopathic manufacturing procedure:	Produced in accordance with the German Homeopathic Pharmacopoeia (HAB) monograph "Arnica montana ex planta tota" Method 3c.
Description of vehicles used:	Ethanol 30% w/w Ethanol 43% w/w Ethanol 15% w/w Ethanol 88% w/w Ethanol 100% w/w

Arnica montana mother tincture is a yellow liquid with a sharp, characteristic odour and spicy, aromatic, slightly burning taste. Arnica Montana is grown organically in the UK.

Manufacture

The whole fresh flowering plants are collected from an isolated field, away from sources of pollution. Collection is manual and no chemical treatments are used pre or post harvest. After collection the plant material is sent overnight under ambient conditions to a factory.

The mother tincture of Arnica montana is produced from the whole fresh flowering plant in accordance with the German Homeopathic Pharmacopoeia (HAB) monograph "Arnica montana ex planta tota".

A detailed description of the process has been included. In summary, the plant material is ground, mixed with alcohol and then, after an appropriate period, pressed and filtered. The resulting liquid is the mother tincture.

The manufacturing process is in accordance with Good Manufacturing Practice (GMP).

Control of the Herbal Substance

The raw material, Arnica montana, is described in an official pharmacopoeia (HAB) and the applicant refers to the test specifications mentioned therein. As Arnica montana is described in an official pharmacopoeia, the analytical tests do not require further validation.

Certificates of analysis for the raw material, Arnica montana, have not been submitted. This is satisfactory as the raw material undergoes preliminary treatment and processing prior to manufacture.

The applicant confirms that the ethanol and purified water used to prepare the mother tincture comply with the specifications of the Ph. Eur. Certificates of analysis have been provided to confirm this.

Certificate of analysis for batches of Arnica montana mother tincture have been supplied, demonstrating compliance with the test specification.

Reference Standards or Materials
Satisfactory certificates of analysis are provided.

Container Closure System
Satisfactory details of the container closure system used to store the active ingredient are provided and confirmation has been given that all components of the container closure system comply with Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Stability data for batches of Arnica montana tincture have been provided. The real time stability data confirm that the mother tincture remains stable over a 36 month period when stored in an ambient environment. A shelf life of 36 months is, therefore, acceptable.

The applicant confirms that dilutions made from the mother tincture will be assigned the same shelf life as the original stock, unless freshly prepared for immediate use.

HOMEOPATHIC MEDICINAL PRODUCT: ARNICARE ARNICA 30C PILLULES

Description and Composition of the Homeopathic Product
The finished product is a 30c homeopathic potency of Arnica montana impregnated into white to off-white spherical pillules composed of sucrose and lactose.

The excipients used to manufacture the homeopathic medicinal product are lactose, sucrose and purified water. All excipients are considered to be compatible and do not influence the performance of the product. All excipients used comply with their respective European Pharmacopoeial monograph. Certificates of analysis (CoA) for the excipients have been provided by the suppliers.

A certificate in relation to lactose and transmissible spongiform encephalopathy (TSE) requirements has been received from the suppliers.

No overages are used.

Manufacture
The manufacturing of the product is by a standard process which has been fully validated. The in-process controls of the critical steps of the manufacturing process to ensure the quality of the product have been described and are considered adequate.

Control of 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 packs of 84 pillules that are packed in a Type I neutral glass container with polypropylene outer. The container contents are enclosed using a polypropylene dispenser mechanism with tamper – evident seal. The components of the primary packaging system comply with Directive 2002/72 relating to contact with foodstuffs.

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

Based on the results, a proposed shelf life of 60 months with the storage condition "Do not store above 25^{o}C" is justified.

PRODUCT LITERATURE

The product literature (Summary of Product Characteristics and labelling) for this product are pharmaceutically satisfactory.

Label mock ups were 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 labelling 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.

ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY

This product is considered satisfactory and a homeopathic marketing authorisation should be granted.

PRECLINICAL ASSESSMENT

NONCLINICAL ASPECTS

Arnica montana is a plant of the Asteraceae family and is only administered orally to humans at homeopathic dilutions. The applicant has provided a non-clinical report, including a short literature review, to demonstrate the level of toxicity of Arnica montana.

NONCLINICAL OVERVIEW

The safety data which must be submitted by the applicant is set out on 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 applicant has applied to authorise a 30c potency of Arnica, diluted to 10^{30} and currently holds a homeopathic registration certificate for dilutions of Arnica 4x to 200c inclusive for oral use, fulfilling criteria (b) and (c) above.

CONCLUSION

Two of the criteria for exemption from submitting safety data are fulfilled and no further safety data is required to establish the safe use of the product in the indications sought.

A homeopathic marketing authorisation can be granted.

CLINICAL ASSESSMENT

LEGAL STATUS

General sales list (GSL) is applicable for the dilution of Arnica (30c) to be registered.

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. The applicant has provided homeopathic provings and a published scientific literature review.

Homeopathic provings

Homeopathic provings of Arnica are cited in many homeopathic materia medica, such as Clarke and Boericke. The applicant has provided bibliographic evidence for historical homeopathic provings.

Published scientific literature review

The applicant has provided a bibliographic reference documenting a summary of clinical trials using arnica in homeopathic dilutions. The summary refers to studies where Arnica had been administered in a number of clinical conditions.

The applicant has also provided further details of eleven published clinical studies investigating the clinical effects of arnica. The studies were performed under randomised, double blind conditions and were carried out to investigate the post operative clinical actions of arnica, such as pain relief and bruising.

The results of the clinical trials and studies provided were not conclusive in establishing the clinical effects of arnica but indicated that there may be a trend towards demonstrating some beneficial effects of arnica in some situations.

PROPOSED INDICATION

The applicant has proposed the following:

‘A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of sprains, muscular aches and bruising and swelling after contusions. ’

The proposed indications are acceptable for a national rules application and are within the permitted indications currently authorised for Arnica products.

CONCLUSION

On the basis of the data provided a homeopathic marketing authorisation may be granted.

OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type.

EFFICACY AND SAFETY
The applicant has provided supporting evidence (homeopathic provings and literature references) to fulfil the requirements for this type of application, as it relates to the indications sought.

The SPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified.

ARNICARE ARNICA 30C PILLULES

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received an application under the Homeopathic National Rules Scheme (Article 16.2) on 29 May 2007
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 1 July 2007
3	Following assessment of the application the MHRA requested further information relating to the quality dossier and product literature on 1 October 2007. The applicant responded to the MHRA's requests, providing further information on 10 January 2008
4	Following assessment of the applicant's response the MHRA requested further information relating to the quality dossier and product literature on 19th April 2008. The applicant responded to the MHRA's requests, providing further information on the quality dossier on 30 May 2008.
5	Following assessment of the applicant's response the MHRA requested further information relating to the quality dossier and product literature in October 2008. The applicant responded to the MHRA's requests, providing further information on the quality dossier on 22 January 2009
6	Following assessment of the response the MHRA requested further information relating to the quality dossier on 2 March 2009. The applicant responded to the MHRA's requests, providing further information on the quality dossier on 6 April 2009
7	An National Rules marketing authorisation was granted on 24 April 2009

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Arnicare Arnica 30c pillules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Arnica Montana 30c (GHP)

For excipients, see section 6.1

3 PHARMACEUTICAL FORM

pillules
white to off-white spherical

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of sprains, muscular aches and bruising and swelling after contusions.

4.2 Posology and method of administration

Adults and children: Take 2 pillules every 2 hours for the first 6 doses, then 4 times daily until symptoms improve for up to a maximum of 7 days.
Pillules should either be chewed or placed under the tongue until dissolved.

4.3 Contraindications

Do not use in cases of known hypersensitivity to Arnica preparations, other members of the Asteraceae (Compositae) family, or any of the excipients.

4.4 Special warnings and precautions for use

Keep all medicines out of reach and sight of children.
Do not use if seal is broken.
Handle carefully, homeopathic medicine in an inner glass vial.
If the condition worsens, or if symptoms persist for more than 7 days, or if adverse events occur, consult a healthcare practitioner.

Contains lactose and sucrose - Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency of glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 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. Although no adverse events have been observed, the use of this product during pregnancy should be avoided unless under the guidance of a medical practitioner.

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

4.7 Effects on ability to drive and use machines

Arnica has no influence on the ability to drive and use machines.

4.8 Undesirable effects

None known

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
Sucrose

6.2 Incompatibilities

None known

6.3 Shelf life

60 months

6.4 Special precautions for storage

Do not store above 25^0C.

6.5 Nature and contents of container

Container: Type I neutral glass with polypropylene outer. Closure: Polypropylene dispenser mechanism with tamper – evident seal.
Pack size: 84 pillules.

6.6 Special precautions for disposal

Return any unused medicine to your pharmacist for safe disposal.

7 MARKETING AUTHORISATION HOLDER

A. Nelson & Co. Ltd
5 Endeavour Way
Wimbledon
London
SW19 8UH

8 MARKETING AUTHORISATION NUMBER(S)

NR 01175/0181

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/04/2009

10 DATE OF REVISION OF THE TEXT

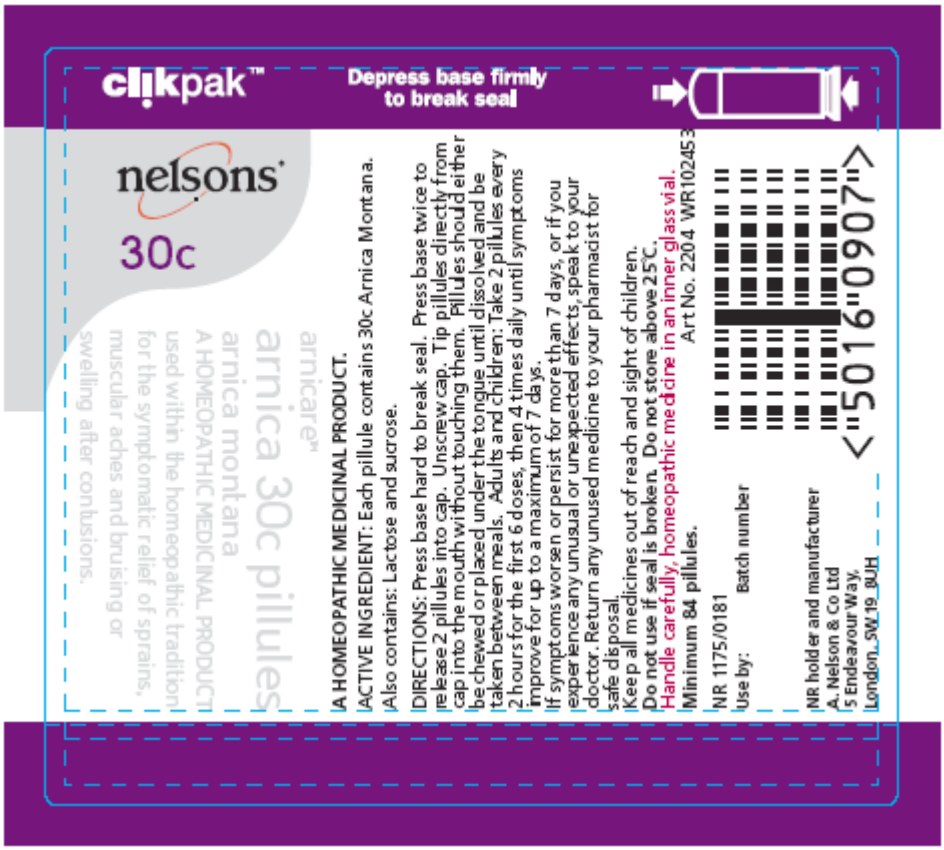
24/04/2009

PATIENT INFORMATION LEAFLET

In accordance with Article 58 of Directive 2001/83 as amended, a patient information leaflet has not been supplied as all of the necessary information is contained on the outer or immediate packaging.

LABELLING

Label:



Cartons


nelsons®
arnicare™
arnica 30c pillules
84 pillules
84 pillules
84 pillules
84 pillules
A HOMEOPATHIC MEDICINAL PRODUCT
Used within the homeopathic tradition for the symptomatic relief of sprains, muscular aches and bruising or swelling after contusions.
WARNING
If symptoms worsen or persist for more than 7 days, or if you experience any unusual or unexpected effects, speak to your doctor.
This product contains lactose and sucrose. If you have been advised by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.
If you are allergic to any of the ingredients in this medicine, consult your doctor before taking this medicine.
If you are taking any other medicines, including those bought without a doctor's prescription, consult your doctor or pharmacist before taking this medicine.
arnicare™
arnica 30c pillules
If pregnant or breastfeeding, consult your doctor before use.
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 take too much of this product (overdose) speak to a doctor/ pharmacist and take this label with you.
Keep all medicines out of reach and sight of children.
Do not use if seal is broken.
Do not store above 25°C.
If the medicine shows any signs of deterioration, consult your pharmacist before using this medicine. Return any unused medicine to your pharmacist for safe disposal.
Do not use after expiry date shown on the carton and container label.
nelsons®
arnicare™
arnica 30c pillules
arnica montana
A HOMEOPATHIC MEDICINAL PRODUCT
used within the homeopathic tradition for the symptomatic relief of sprains, muscular aches and bruising or swelling after contusions.
arnicare™
arnica 30c pillules
ACTIVE INGREDIENT
Each pillule contains 30c Arnica Montana.
Also contains: Lactose and Sucrose.
Handle carefully, homeopathic medicine in an inner glass vial.
Minimum 84 white to off-white pillules.
DIRECTIONS
Press base hard to break seal.
Press base twice to release 2 pillules into cap. Unscrew cap.
Tip pillules directly from cap into mouth without touching them. Pillules should either be chewed or placed under the tongue until dissolved and be taken between meals.
ADULTS AND CHILDREN
Take 2 pillules every 2 hours for the first 6 doses, then 4 times daily until symptoms improve for up to a maximum of 7 days.
NR 1175/0181
NR holder and manufacturer
A. Nelson & Co. Ltd,
5 Endeavour Way, London,
SW19 8UH
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BBE:
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