IPAR

Public Assessment Report for a
Homeopathic Medicinal Product
for Human Use

HOA Holder

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I. 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 Nelsons Arnicare Arnica cream, containing Arnica montana.

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.

II. QUALITY ASPECTS

This application is for Nelsons Arnicare Arnica cream. The active ingredient of Nelsons Arnicare Arnica cream is derived from the Arnica montana plant.

QUALITATIVE AND QUANTITATIVE COMPOSITION
1 g cream contains:
Arnica montana tincture 1X (0.9% w/w)

Excipient(s) with known effect:
Cetostearyl alcohol 2.75% w/w
Propyl parahydroxybenzoate (E216) 0.15% w/w
Methyl parahydroxybenzoate (E218) 0.30% w/w

(Full composition P1 below)

II.1 S.1 Homeopathic raw material

The homeopathic raw material specification for Arnica montana is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.2 S.2 Homeopathic stock

The homeopathic stock Arnica montana is described in an Official pharmacopoeia of a Member State, the German Homeopathic Pharmacopoeia and is manufactured in accordance with the principles of good manufacturing practice (GMP).

The homeopathic stock specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition
Smooth white to off-white cream

Composition of the medicinal product.
Arnica montana tincture 1X (0.9% w/w)
Purified water
Glyceryl monostearate & Macrogol stearate
Apricot kernel oil
Theobroma oil
Glycerol E422
Cetostearyl alcohol & PEG-20 Stearate
Cetostearyl alcohol
Cetyl palmitate
Glyceryl monocaprylate
Methyl parahydroxybenzoate E218
Propyl parahydroxybenzoate E216

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
Nelsons Arnicare Arnica Cream does not contain any ingredients of human or animal origin, 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 cream, 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 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 product is presented as an Epoxy phenolic lacquered aluminium tube with polypropylene/polyethylene cap.

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 have been provided in accordance with EU guidelines demonstrating the stability of the product for 3 years when stored at '*not above 25*°C'.

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 Nelsons Arnicare Arnica cream.

III. NON-CLINICAL ASPECTS

Nelsons Arnicare Arnica Cream is a homeopathic medicinal product as defined by Article 16 of Directive 2001/83/EC, as amended.

No preclinical studies have been submitted. This is acceptable for this type of application according to the regulations. The product *Nelsons Arnicare Arnica Cream* conforms to subparagraph 11.3 of the regulations and therefore is deemed appropriate for the proposed use.

An expert report on safety has been provided which includes an appropriate review of the available literature.
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 highly dilute active ingredients and therefore pose no environmental risk.

IV. CLINICAL ASPECTS

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

Nelsons Arnicare Arnica Cream is a homeopathic medicinal product used for: '*A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of bruises*'.

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 Nelsons Arnicare Arnica Cream 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 Nelsons Arnicare Arnica Cream 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 a bibliographic review of the safety data together with an expert report.
There are no safety issues pertaining to the use of this product as proposed. In addition treatment is being recommended for a maximum of two weeks. 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; '*If the symptoms worsen or persist after using the product for two weeks, a doctor or qualified healthcare practitioner should be consulted*.', is present on the packaging.

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

Contraindications

Hypersensitivity to the active ingredient or to plants of the Asteraceae (Compositae) family or to any of the excipients listed in 6.1.

Special warnings and precautions for use

Do not exceed the stated dose
Avoid contact with eyes and mucous membranes.
Not to be applied to broken or irritated skin. Discontinue use if skin becomes red, dry or irritated.
This product is not recommended for children under 2 years of age and medical advice should be sought.
This product contains Cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).
This product contains propyl parahydroxybenzoate (E216) and methyl parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed).

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, expert report 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.

V. OVERALL CONCLUSIONS

The product Nelsons Arnicare Arnica Cream is manufactured by Nelsons using the Pharmacopoeial (GHP) active ingredient Arnica montana and excipients according to Ph. Eur., Official Pharmacopoeias or manufacturer's specifications. Manufacturing processes are well described and controlled and appropriate for this type of topical 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 Nelsons Arnicare Arnica Cream.

The product Nelsons Arnicare Arnica Cream contains the active ingredient Arnica montana which is controlled by a monograph in the GHP. The active is diluted to 1X in the finished product and adheres to the legislation with respect to safety requirements. All excipients in Nelsons Arnicare Arnica Cream are 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.
Nelsons Arnicare Arnica Cream has been proposed as a treatment for: A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of bruises.
Homeopathic literature and provings support the use of the active ingredient Arnica montana for this indication. Since bruises are considered to be mild self-limiting conditions, they are 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 two weeks.

The HPRA, on the basis of the data submitted, considered that Nelsons Arnicare Arnica Cream 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 Nelsons Arnicare Arnica Cream is granted.

VI. REVISION DATE

December 2020

VII. UPDATES

Procedure number	Product Information affected	Date of start of procedure	Date of end of procedure	Approval/non approval
Transfer CRN009D69	SmPC section 7, 8, 10 Package Leaflet New Registration Holder: Nelsons GmbH New HOA number: HOA22892/004/001	N/A	18/12/2020	Approved 18/12/2020