

Boots Pharmaceuticals Bruise Relief Arnica cream

THR 01175/0398

UKPAR

TABLE OF CONTENTS

| | |
|------------------------------------|---------|
| Lay summary | Page 2 |
| Scientific discussion | Page 3 |
| Steps taken for assessment | Page 10 |
| Summary of Product Characteristics | Page 11 |
| Patient Information Leaflet | Page 12 |
| Labelling | Page 13 |

BOOTS PHARMACEUTICALS BRUISE RELIEF ARNICA CREAM

THR 01175/0398

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted A Nelson & Co Limited a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Boots Pharmaceuticals Bruise Relief Arnica Cream (Traditional Herbal Registration number: THR 01175/0398) on 24 April 2013. Boots Pharmaceuticals Bruise Relief Arnica Cream is available without prescription and can be bought from pharmacies and other outlets.

Boots Pharmaceuticals Bruise Relief Arnica Cream is a traditional herbal medicinal product used for the symptomatic relief of bruises, based on traditional use only.

This registration is based exclusively upon evidence of the use of tincture from Arnica, as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.

BOOTS PHARMACEUTICALS BRUISE RELIEF ARNICA CREAM

THR 01175/0398

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

| | |
|--|--------|
| Introduction | Page 4 |
| Pharmaceutical assessment | Page 5 |
| Non-clinical assessment | Page 7 |
| Clinical assessment | Page 8 |
| Overall conclusions and benefit- risk assessment | Page 9 |

INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Boots Pharmaceuticals Bruise Relief Arnica Cream (Traditional Herbal Registration number: THR 01175/0398) on 24 April 2013. This product is on the general sales list (GSL).

A product licence of right (PLR) was originally granted to A Nelson & Co Limited for this product. The PLR was reviewed and a product licence (PL 01175/5037R) was granted to A Nelson & Co Limited on 27 June 1990. A Nelson & Co Limited has committed to cancel PL 01175/5037R following the grant of the Traditional Herbal Registration Certificate.

This THR application was made under Article 16.c of Directive 2001/83 EC in accordance with arrangements to transfer certain herbal products with a Marketing Authorisation to a THR (according to MHRA Guidance dated January 2009). The application falls within the simplified THR application Category A, as no significant changes have been made to the formulation of the product. No new data were submitted, nor was it necessary for this application, as the data are essentially identical to those of the existing product.

PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: **ARNICA WHOLE PLANT**

Scientific name of the plant: *Arnica montana* L.

Plant family: Asteraceae

The herbal substance is acceptable.

HERBAL PREPARATION: **ARNICA TINCTURE**

Extraction solvent: Ethanol 57% v/w

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

HERBAL PRODUCT: **BOOTS PHARMACEUTICALS BRUISE
RELIEF ARNICA CREAM**

Description and Composition of the Herbal Product

Boots Pharmaceuticals Bruise Relief Arnica Cream is a smooth white to off-white cream. Each gram of cream contains:

9.0 mg tincture of Arnica whole plant (*Arnica montana* L.) (1:10), equivalent to 0.9 mg Arnica whole plant and the pharmaceutical excipients purified water, white soft paraffin, polawax GP 200 (cetostearyl alcohol, PEG-20 stearate), methyl parahydroxybenzoate E218, propyl parahydroxybenzoate E216 and honey. The formulation is in line with that of the already licensed product. It is, therefore, acceptable.

Manufacture

The manufacturing process is in line with that of the already licensed product and is satisfactory.

Finished Product Specification

The finished product specification is in line with that of the already licensed product and is satisfactory.

Container Closure System

Boots Pharmaceuticals Bruise Relief Arnica Cream is stored in epoxy phenolic lacquered aluminium tubes with a polypropylene/polyethylene cap in pack sizes of 25 g, 30 g and 50 g tubes.

The packaging has been used to store the already licensed product and is satisfactory.

Stability

The product has a shelf-life of 3 years when the storage precautions 'Do not store above 25°C' and 'Store in the original container' are applied. This is in line with the already licensed product and is appropriate.

Summary of Product Characteristics, product labels and Patient Information Leaflet

All product literature is in line with that of the already licensed product, with some details amended in line with other products registered under the THR scheme.

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.

ASSESSOR'S OVERALL CONCLUSION

It is recommended that a Traditional Herbal Registration can be granted.

NON-CLINICAL ASSESSMENT

INTRODUCTION

No new non-clinical data have been supplied with this application and none are required for an application of this type.

Assurance has been given that the results of genotoxicity testing will be provided by the renewal date of the Traditional Herbal Registration.

PRODUCT LITERATURE

All product literature is satisfactory from a non-clinical point of view.

ASSESSOR'S OVERALL CONCLUSION

It is recommended that a Traditional Herbal Registration can be granted.

CLINICAL ASSESSMENT

INTRODUCTION

The clinical particulars for Boots Pharmaceuticals Bruise Relief Arnica Cream are identical to those for the already licensed product. This is satisfactory.

PRODUCT LITERATURE

All product literature is medically satisfactory.

ASSESSOR'S OVERALL CONCLUSION

It is recommended that a Traditional Herbal Registration can be granted.

OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY

Boots Pharmaceuticals Bruise Relief Arnica Cream is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

NON-CLINICAL

No new non-clinical data were submitted and none are required for an application of this type. The results of genotoxicity testing will be provided before the THR is renewed.

EFFICACY

No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products.

SAFETY

No new or unexpected safety concerns arose from this application.

BENEFIT-RISK ASSESSMENT

The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and a THR should be granted.

BOOTS PHARMACEUTICALS BRUISE RELIEF ARNICA CREAM

THR 01175/0398

STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the Traditional Herbal Registration application on 04 February 2013
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 13 February 2013
- 3 Following assessment of the application the MHRA requested further information relating to the dossier on 11 March 2013.
- 4 The applicant responded to the MHRA's requests, providing further information on the dossier on 24 April 2013.
- 5 A THR was granted on 24 April 2013

SUMMARY OF PRODUCT CHARACTERISTICS

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

LABELLING



| BRAILLE CONVERSION – English Alphabet |
|--|
| |
| <p style="font-size: 1.2em; margin: 0;">Boots Bruise Relief Arnica Cream</p> |



BRUISE RELIEF ARNICA Cream

Arnica montana

✓ A traditional herbal medicinal product used for the symptomatic relief of bruises, based on traditional use only.

30 g e

Use By

Read all of the leaflet for full instructions.

✓ How to use this medicine

Check the tube seal is not broken before first use. If it is, do not use the cream.

| Age | How to use | How often to use |
|----------------------------------|-------------------------------|-----------------------------|
| Adults, the elderly and children | Apply gently to bruised areas | Four times a day, as needed |

For use on the skin only. Keep away from eyes. Do not apply to broken or irritated skin. Stop using this product if a skin rash or contact dermatitis appear. If symptoms worsen, or do not go away, talk to your doctor.

How to store this medicine

Do not store above 25°C.

Keep all medicines out of the sight and reach of children.

Use by the date on the end flap of the carton and the tube edge.

Active ingredient

Each gram of cream contains: 9.0 mg tincture of Arnica Whole Plant (*Arnica montana* L.) (1:10) equivalent to 0.9 mg Arnica Whole Plant Extraction solvent Ethanol 57% v/v. Also contains purified water, white soft paraffin, polywax GP 200 (cetostearyl alcohol, PEG-20 stearate), methyl parahydroxybenzoate (E218), honey, propyl parahydroxybenzoate (E216). See leaflet for more information.

THR 01175/0398

Manufactured for The Boots Company PLC Nottingham NG2 3AA by the Traditional Herbal Registration holder A Nelson & Co Limited 5-9 Endeavour Way Wimbledon London SW19 8UH WR403012 Art no: 4023

Lot

