Weleda Arnica Massage Balm

THR 00298/0277

UKPAR

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WELEDA ARNICA MASSAGE BALM

THR 00298/0277

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Weleda (UK) Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Weleda Arnica Massage Balm (Traditional Herbal Registration number: THR 00298/0277) on 23 May 2012. Weleda Arnica Massage Balm is available without prescription and can be bought from pharmacies and other outlets.

Weleda Arnica Massage Balm is a traditional herbal medicinal product used for the symptomatic relief of rheumatic pain, muscular pain and stiffness, backache, fibrositis, bruising, cramp, sprains and minor sports injuries, based on traditional use only. The active ingredients in Weleda Arnica Massage Balm come from the dried flowers of the Arnica plant, which is also known as *Arnica montana* L., and the dried leaves of the Birch tree, which is also known as *Betula pendula* Roth.

This registration is based exclusively upon evidence of the use of Arnica flowers and Birch leaves as traditional herbal medicines 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.
SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Weleda Arnica Massage Balm (THR 00298/0277) to Weleda (UK) Ltd on 23 May 2012. This product is on the general sales list (GSL).

A product licence of right (PLR) was granted to Weleda (UK) Ltd for this product in 1972. The PLR was reviewed and a product licence (PL 00298/5528R) was granted to Weleda (UK) Ltd for this product (under the name Massage Balm with Arnica) on 27 April 1992. PL 00298/5528R was cancelled on 25 May 2012.

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.
HERBAL SUBSTANCE: ARNICA FLOWER
Scientific name of the plant: Arnica montana L.
Plant family: Asteraceae
The herbal substance complies with the Ph Eur monograph and is, therefore, acceptable.

HERBAL SUBSTANCE: BIRCH LEAF
Scientific name of the plant: Betula pendula Roth.
Plant family: Betulaceae
The herbal substance complies with the Ph Eur monograph and is, therefore, acceptable.

HERBAL PREPARATION: ARNICA FLOWER AND BIRCH LEAF LIQUID EXTRACT
Extraction solvents: Ethanol (96% v/v)
Sunflower oil (2.3/97.7)
The herbal preparation is used in the already licensed product. It is, therefore, acceptable.

HERBAL PRODUCT: WELEDA ARNICA MASSAGE BALM
Description and Composition of the Herbal Product
Weleda Arnica Massage Balm is a clear, yellow-green, cutaneous oil. 1g of balm contains 0.70g of liquid extract from dried Arnica flowers and dried Birch leaves. The extraction solvents are ethanol and sunflower oil. The remaining excipients are rosemary oil, lavender oil and lavandin oil. The formulation is identical to that of the already licensed product. It is, therefore, acceptable.

Manufacture of Herbal Product
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
The balm is packed into 50 ml, 100 ml or 200 ml glass bottles with a white screw cap and red tamper evident ring. Not all licensed pack sizes may be marketed. The 50 ml and 200 ml bottles are green and the 100 ml bottles are blue. This type of packaging has been used to store the already licensed product and is satisfactory.
**Stability of Herbal Product**
Product shelf-lives of 4 years for product stored in the 50 and 100 ml bottles and of 2 years for product stored in the 200 ml bottles were applied to the already licensed product and are appropriate when the storage precaution ‘Do not store above 25°C’ and is applied. Likewise, the shelf-life of 3 months for product stored in bottles that have been opened was applied to the already licensed product and is appropriate.

**Summary of Product Characteristics, label 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.
PRECLINICAL ASSESSMENT

INTRODUCTION
No new preclinical data have been supplied with this application and none is 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 preclinical 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 Weleda Arnica Massage Balm 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
Weleda Arnica Massage Balm is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

PRECLINICAL
No new preclinical 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 preclinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and a THR should be granted.
WELEDA ARNICA MASSAGE BALM

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STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Traditional Herbal Registration application on 27 January 2012

2. Following standard checks and communication with the applicant the MHRA considered the application valid on 14 March 2012

3. Following assessment of the application the MHRA requested information relating to the dossier on 20 March 2012

4. The applicant responded to the MHRA’s request providing further information on the dossier on 17 May 2012

5. A THR was granted on 23 May 2012
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Weleda Arnica Massage Balm.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
1g of balm contains

0.70g of liquid extract from: dried flowers of Arnica (equivalent to 0.046g Arnica montana L) and dried leaves of Birch (equivalent to 0.046g Betula pendula Roth).

Extraction solvent: Ethanol 96% v/v / Sunflower Oil (2.3/97.7).

0.039g of Rosemary Oil (Rosmarinus officinalis L.)

0.0095g of Lavender Oil (Lavandula angustifolia Mill.).

0.0095g of Lavandin Oil (Lavandula hybrida)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Cutaneous Oil.

A clear yellow-green oil.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used for the symptomatic relief of rheumatic pain, muscular pain and stiffness, backache, fibrositis, bruising, cramp, sprains and minor sports injuries, based on traditional use only.

4.2 Posology and method of administration
For cutaneous use only.

Wash hands before and after use.

Adults, the elderly and children over 12 years: Apply sparingly to the affected area with gentle massage three to four times daily.

The use in children under 12 years of age is not recommended (see Section 4.4 Special warnings and precautions for use).
4.3 **Contraindications**
Hypersensitivity to *Arnica montana* or other species of the Asteraceae (Compositae) family.

Hypersensitivity to Birch, Rosemary or Lavender species or to any of the other ingredients in the product.

4.4 **Special warnings and precautions for use**
Do not exceed the stated dose.

If the condition worsens, or if symptoms persist for more than two weeks, or if adverse events not mentioned in the package leaflet occur, consult a qualified healthcare practitioner.

If articular pain accompanied by swelling of joint, redness or fever are present a doctor should be consulted.

The use of this product in children under 12 years of age is not recommended because data are not sufficient and medical advice should be sought.

For cutaneous use only.

Do not use on broken or irritated skin. Avoid contact with eyes and mucous membranes. Discontinue use if redness, irritation or dry skin occurs.

4.5 **Interaction with other medicinal products and other forms of interaction**
No interaction studies have been performed

4.6 **Fertility, pregnancy and lactation**
The safety of the product during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Studies on the effects on fertility have not been performed.

4.7 **Effects on ability to drive and use machines**
Not relevant.

4.8 **Undesirable effects**
Hypersensitivity (contact dermatitis, itching skin rash and asthma) has been reported. The frequency is not known.
If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

4.9 **Overdose**
No case of overdose has been reported.

In the unlikely event of internal ingestion, due to the irritant effect of the product, symptoms of intoxication may include gastro-intestinal and nervous system disturbances; dizziness, diarrhoea, shivering and palpitations.
Respiratory difficulties may occur at very high doses. Treatment of overdose: the stomach should be emptied by aspiration or lavage if the patient has not already vomited. Demulcent drinks such as milk should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data
Tests on reproductive toxicity, genotoxicity or carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sunflower Seed Oil
Ethanol

6.2 Incompatibilities
Not applicable

6.3 Shelf life
Shelf life of product as packaged for sale:

4 years: 50, 100 ml pack sizes
2 years: 200 ml pack size

Shelf-life after first opening

3 months.

6.4 Special precautions for storage
Do not store above 25°C

6.5 Nature and contents of container
Green glass bottle, white screw cap and red tamper evident ring.
Pack size 50ml

Blue glass bottle, white screw cap and red tamper evident ring.
Pack size 100ml

Green glass bottle, white screw cap and red tamper evident ring.
Pack size 200ml
Not all pack sizes may be marketed.

6.6 Special precautions for disposal
There are no special precautions for disposal.

7 MARKETING AUTHORISATION HOLDER
Weleda (UK) Ltd
Heanor Road
Ilkeston
Derbyshire DE7 8DR, UK

8 MARKETING AUTHORISATION NUMBER(S)
THR 00298/0277

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
23/05/2012

10 DATE OF REVISION OF THE TEXT
23/05/2012
PRODUCT INFORMATION LEAFLET

WELEDA ARNICA MASSAGE BALM

Traditional Herbal Medicinal Product

1g of balm contains the following ingredients:
0.70g Arnica flowers liquid extract; 0.70g Birch leaves liquid extract; 0.039g Rosemary oil; 0.0096g Lavender oil; 0.00085g Lavandin oil.

PATIENT INFORMATION

Read this leaflet carefully because it contains important information for you.

Keep this leaflet as you may need to read it again.

Ask your pharmacist or qualified healthcare practitioner if you need more information or advice.
You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve after two weeks.

If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor, pharmacist or qualified healthcare practitioner.

In this leaflet:
1. What Weleda Arnica Massage Balm is and what it is used for
2. Before you use Weleda Arnica Massage Balm
3. How to use Weleda Arnica Massage Balm
4. Possible side-effects
5. How to store Weleda Arnica Massage Balm
6. Further information

1. What the product is and what it is used for

Weleda Arnica Massage Balm is a traditional herbal medicinal product used for the symptomatic relief of rheumatic pain, muscular pain and stiffness, backache, fibrositis, bruising, cramp, sprains and minor sports injuries. This is based on traditional use only.

2. Before you use this product

Do not use Weleda Arnica Massage Balm if you are allergic to any of the ingredients (see Section 6), if you are pregnant, breastfeeding or under 12 years of age.

- Consult your doctor, pharmacist or qualified healthcare practitioner if:
  - you are suffering from joint pain which is accompanied by swelling of the joint, redness or fever.

Special warnings and precautions for use:

Weleda Arnica Massage Balm is for external use only.
Do not apply to broken skin.
Avoid contact with the eyes and mucous membranes.
In some patients Weleda Arnica Massage Balm may cause irritation of the skin when it is first applied. If you experience any redness, itching or dry skin discontinue use and consult your doctor or pharmacist.
3 How to use Weleda Arnica Massage Balm

Weleda Arnica Massage Balm is for application to the skin

**Directions:** Shake the bottle

**Adults, the elderly and children over 12 years:** Wash hands before and after use. Apply sparingly to the affected area with gentle massage three to four times daily. For maximum effect apply after a warm bath or shower while the skin is still damp. Do not exceed the stated dose.

4. Possible side effects

Like all medicines Weleda Arnica Massage Balm can cause side effects although not everybody gets them. Weleda Arnica Massage Balm can cause contact dermatitis, an itchy skin rash or asthma. If your skin feels itchy, you develop a patch of dry, inflamed skin or a rash or you experience difficulty breathing you should stop using Weleda Arnica Massage Balm and consult your doctor, pharmacist or qualified healthcare practitioner.

If you experience any side effects, if your symptoms worsen or do not improve after two weeks, consult your doctor, pharmacist or qualified healthcare practitioner.

5. How to store Weleda Arnica Massage Balm

- keep out of the reach and sight of children
- do not store above 25°C
- do not use after the expiry date on the carton
- discard after 3 months of first opening
- return any unused medicine to your pharmacist for safe disposal

6. Further Information

1g of balm contains 0.70g of liquid extract from: dried flowers of Arnica (equivalent to 0.046g Arnica montana L.); dried leaves of Birch (equivalent to 0.046g Betula pendula Roth.), 0.039g of Rosemary Oil and 0.0095g Lavender oil; 0.0095g Lavandin oil.

**Extraction solvent:** Ethanol 96% v/v / Sunflower Oil (2.3/97.7).

**Pack Description:** Weleda Arnica Massage Balm is a clear, yellow-green oil presented in a glass dropper bottle. Three pack sizes are available - 50ml, 100ml and 200ml. Not all pack sizes may be marketed.

Traditional Herbal Registration holder and manufacturer: Weleda Arnica Massage Balm is manufactured and marketed by Weleda UK Ltd, Heanor Road, Ilkeston, Derbyshire DE7 8DR

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You can help to make medicines safer by reporting any 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 freephone 0800 100 3352 (available 10am-2pm Monday - Friday).

Braille version

To request a copy of this leaflet in Braille or large print, or to listen to an audio version, please call free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information:

**Product name:** Weleda Arnica Massage Balm **Reference number:** THR 00298/0277

This service is provided by the Royal National Institute of Blind People.

This leaflet was last revised: March 2012
50 ml pack

Labels:

A traditional herbal medicinal product used for the symptomatic relief of rheumatic pain, muscular pain and stiffness, bad aches, fibrositis, bruising, cramp, sprains and minor sports injuries. This is based on traditional use only.

Active ingredients: 1g of balm contains 0.70g of liquid extract from: dried flowers of Arnica (equivalent to 0.046g Arnica montana L.), dried leaves of Birch (equivalent to 0.046g Betula pendula Roth.), 0.035g of Rosemary Oil and 0.0035g Lavender oil; 0.0095g Lavandin oil. Extraction solvent: Ethanol 96% v/v / Sunflower Oil (2.3)/97.7%.

Discard 3 months after opening
Do not store above 25°C
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Directions: For application to the skin.
Adults, the elderly and children over 12 years: Apply sparingly to the affected area with gentle massage three to four times daily.

For maximum effect apply after a warm bath or shower while the skin is still damp.

Shake the bottle.
Please read the enclosed leaflet before use.
Do not apply to broken skin.
Keep all medicines out of the reach and sight of children.

Contents 50ml
L706002/13

Traditional Herbal Registration holder: Weleda (UK) Ltd., Heanor Road, Ilkeston, Derbyshire, DE7 8DR, UK.
100 ml pack

Labels:

A traditional herbal medicinal product used for the symptomatic relief of muscular pain and stiffness, backache, fibromyalgia, bruising, cramps, sprains and minor sports injuries. This is based on traditional use only.

Active ingredients: 1g of balm contains 0.70g of liquid extract from dried flowers of Arnica (equivalent to 0.046g Arnica montana L.); dried leaves of Birch (equivalent to 0.046g Betula pendula Roth.), 0.03g of Rosemary Oil and 0.0095g Lavender oil; 0.0095g Lavandin oil.

Extraction solvent: Ethanol 96% v/v / Sunflower Oil (2.9/977).

Discard 3 months after opening
Do not store above 25°C
THR 00298/0277

FOR EXTERNAL USE ONLY

Directions: For application to the skin.

Adults, the elderly and children over 12 years: Apply sparingly to the affected area with gentle massage three to four times daily.

For maximum effect apply after a warm bath or shower while the skin is still damp.

Shake the bottle.

Please read the enclosed leaflet before use.

Do not apply to broken skin.

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

Contents 100ml L7089003/13

Traditional Herbal Registration holder: Weleda (UK) Ltd., Hennon Road, Ilkeston, Derbyshire, DE7 6DR, UK.
200 ml pack

Labels:

A traditional herbal medicinal product used for the symptomatic relief of rheumatic pain, muscular pain and stiffness, backache, fibrositis, bruising, cramps, sprains and minor sports injuries. This is based on traditional use only.

Active ingredients: 1g of balm contains 0.70g of liquid extract from dried flowers of Arnica (equivalent to 0.046g Arnica montana L.), dried leaves of Birch (equivalent to 0.046g Betula pendula Roth.), 0.039g of Rosemary Oil and 0.0085g Lavender oil: 0.0095g Lavandin oil.

Extraction solvent: Ethanol 96% v/v / Sunflower Oil (2.3/977).

Discard 3 months after opening
Do not store above 25°C

FOR EXTERNAL USE ONLY

Directions: For application to the skin.

Adults, the elderly and children over 12 years: Apply sparingly to the affected area with gentle massage three to four times daily.

For maximum effect apply after a warm bath or shower while the skin is still damp.

Shake the bottle.

Please read the enclosed leaflet before use.

Do not apply to broken skin.

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

Contents 200ml

L/J085/15/1

Traditional Herbal Registration holder: Weleda (UK) Ltd., Heanor Road, Ilkeston, Derbyshire, DE7 8DR, UK.
Carton:

Weleda Arnica Massage Balm

Active ingredients: 1 g of balm contains 0.75% of liquid extract from dried flowers of Arnica montana L., dried leaves of Birch aquifolium (L.) Desfontaines and Delphinium elatum L., 0.02% of Rosemary oil and 0.005% of Lavender oil. Lavandin oil.

Extraction solvent: Ethanol 36% v/v / Sunflower Oil.

Discard 2 months after opening. Do not store above 35°C.

FOR EXTERNAL USE ONLY

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

Do not use after the expiry date stated.

THR 00298/0277

A traditional herbal medicinal product used for the symptomatic relief of muscular and rheumatic pain. Based on traditional use only.

A traditional herbal medicinal product used for the symptomatic relief of muscular and rheumatic pain. Based on traditional use only.

CUTANEOUS (SKIN) OIL

Adults, the elderly and children over 12 years: Apply sparingly to the affected area with gentle massage three to four times daily. For maximum effect apply after a warm bath or shower while the skin is still damp. Shake the bottle. Please read the enclosed leaflet before use. Do not apply to broken skin. Do not use if:
- you are allergic to any of the ingredients
- you are pregnant or breastfeeding
- under 12 years old
- May stain clothing if used in excess.

Contents: 200ml

Traditional Herb Registration holder: Manufactured and marketed by Weleda UK Ltd., Henon Road, Froxfield, Devizes, Wiltshire, SN10 5BY, UK.