

Weleda Cold Relief Oromucosal Spray

NR 00298/0274

UKPAR

TABLE OF CONTENTS

Lay summary	Page 2
Scientific discussion	Page 3
Steps taken for assessment	Page 14
Summary of Product Characteristics	Page 15
Product Information Leaflet	Page 19
Labelling	Page 22

WELEDA COLD RELIEF OROMUCOSAL SPRAY

NR 00298/0274

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Weleda (UK) Ltd a Homeopathic Marketing Authorisation for the homeopathic medicinal product Weleda Cold Relief Oromucosal Spray (Homeopathic Marketing Authorisation number: NR 00298/0274) on 6 August 2013. This product is available without prescription and can be bought from pharmacies and other outlets.

Weleda Cold Relief Oromucosal Spray is a homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of the common cold, cough associated with the common cold and related flu-like symptoms. This indication is based on *Materia medica* references, published clinical studies and other bibliographic evidence. The active ingredients in Weleda Cold Relief Oromucosal Spray are *Allium cepa* 6X, *Drosera rotundifolia* 6X and *Gelsemium sempervirens* 6X.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Homeopathic Marketing Authorisation could be granted.

WELEDA COLD RELIEF OROMUCOSAL SPRAY

NR 00298/0274

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction	Page 4
Pharmaceutical Assessment	Page 5
Non-clinical and clinical safety assessment	Page 10
Clinical assessment (non safety)	Page 11
Overall conclusion and risk assessment	Page 13

INTRODUCTION

The MHRA granted a Homeopathic Marketing Authorisation for the homeopathic medicinal product Weleda Cold Relief Oromucosal Spray 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. Weleda Cold Relief Oromucosal Spray contains the homeopathic stocks *Allium cepa* 6X, *Drosera rotundifolia* 6X and *Gelsemium sempervirens* 6X. The spray is used for the symptomatic relief of the common cold, cough associated with the common cold, and related flu-like symptoms.

Allium cepa, *Drosera rotundifolia* and *Gelsemium sempervirens* are established homeopathic remedies and their traditional use in homeopathy is well documented. In support of this application to authorise Weleda Cold Relief Oromucosal Spray *Materia medica* references, published clinical studies and other bibliographic evidence have been provided.

PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: *ALLIUM CEPA BULB*
Scientific/Latin name: *Allium cepa* L.
Synonym: Red onion

Manufacture

The red onion plants are cultivated in the UK without the use of artificial fertilizers, pesticides or herbicides. The plants are harvested during the summer then transported directly to the manufacturing facility where they are examined, sorted and washed, where necessary, in running water.

The herbal substance is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP).

Control of the Herbal Substance

The red onion is described in the German Homeopathic Pharmacopoeia (GHP) and its quality is satisfactorily controlled.

Container Closure System

Satisfactory details of the container closure system used to store the herbal substance are provided.

Stability

A shelf-life for the herbal substance is not necessary because it is collected and used in the fresh state.

ACTIVE INGREDIENT

(HOMEOPATHIC STOCK): *ALLIUM CEPA MOTHER TINCTURE*

Extraction solvent: Ethanol 90% V/V

General properties: A light yellow to reddish yellow liquid with a strong onion-like odour and taste

Manufacture

A satisfactory description of the manufacturing process of the homeopathic stock has been provided. The homeopathic stock is prepared according to method 2a of the Ph. Eur. The in-process controls are satisfactorily detailed. Certificates of Analysis for the ethanol and purified water 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.

Certificates of Analysis have been provided for batches of the homeopathic stock, demonstrating satisfactory compliance with the proposed specifications.

Container Closure System

Satisfactory details of the container closure system are provided.

Stability

Stability studies have been carried out and the results support the proposed shelf life of the homeopathic stock.

HERBAL SUBSTANCE: ***DROSERA ROTUNDIFOLIA PLANTS***

Scientific/Latin names: *Drosera rotundifolia; Drosera intermedia*
Hayne; *Drosera anglica* huds.

Synonym: Drosera

Manufacture

The *Drosera* plants are collected from the wild in Finland. They are usually collected mechanically in the second half of July when the plants are just starting to flower. The herbal substance is examined and sorted, before being processed into tincture.

Confirmation has been provided that the herbal substance is collected in line with the Guideline on Good Agricultural and Collection Practice (GACP)/HMPC guideline.

Control of the Herbal Substance

The *Drosera* is described in the GHP and its quality is satisfactorily controlled.

Container Closure System

Satisfactory details of the container closure system used to store the herbal substance are provided.

Stability

A shelf-life for the herbal substance is not necessary because it is collected and used in the fresh state.

ACTIVE INGREDIENT

(HOMEOPATHIC STOCK): ***DROSERA ROTUNDIFOLIA MOTHER***
TINCTURE

Extraction solvent: Ethanol 90% V/V

General properties: A reddish brown liquid

Manufacture

A satisfactory description of the manufacturing process of the homeopathic stock has been provided. *Drosera* mother tincture is manufactured according to method 2a 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.

Certificates of Analysis have been provided for batches of the homeopathic stock, demonstrating satisfactory compliance with the proposed specifications.

Container Closure System

Satisfactory details of the container closure system are provided.

Stability

Stability studies have been carried out and the results support the proposed shelf life of the homeopathic stock.

HERBAL SUBSTANCE: *GELSEMIUM SEMPERVIRENS* ROOTS AND RHIZOMES

Scientific/Latin name: *Gelsemium sempervirens* L.

Synonym of plant name: Gelsemium, Yellow Jasmine, False Jasmine, Wild Woodbine

Manufacture

The *Gelsemium sempervirens* plants are hand collected from the wild in the USA and preserved in 94.9% v/v ethanol immediately after collection.

Confirmation has been provided that pesticides, herbicides or growth promoters are not used and that the herbal substance is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP)/HMPC guideline.

Control of the Herbal Substance

The *Gelsemium sempervirens* is described in the GHP and the applicant refers to the test specifications mentioned therein. As *Gelsemium sempervirens* is described in an official pharmacopoeia, the analytical tests do not require further validation.

Satisfactory Certificates of Analysis for the *Gelsemium sempervirens* herbal substance have been provided.

Container Closure System

Satisfactory details of the container closure system used to store the herbal substance are provided.

Stability

A shelf-life for the herbal substance is not necessary because it is collected and used in the fresh state.

**ACTIVE INGREDIENT
(HOMEOPATHIC STOCK):** **GELSEMIUM SEMPERVIRENS MOTHER
TINCTURE**

Extraction solvent: Ethanol 90 % V/V

General properties: A golden yellow to yellowish brown liquid with
no characteristic odour

Manufacture

A satisfactory description of the manufacturing process of the homeopathic stock has been provided. *Gelsemium sempervirens* mother tincture is manufactured according to method 3a 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.

Certificates of Analysis have been provided for batches of the homeopathic stock, demonstrating satisfactory compliance with the proposed specifications.

Container Closure System

Satisfactory details of the container closure system are provided.

Stability

Stability studies have been carried out and the results support the proposed shelf life of the homeopathic stock.

HOMEOPATHIC MEDICINAL PRODUCT: **WELEDA COLD RELIEF
OROMUCOSAL SPRAY**

Description and Composition of the Homeopathic Product

The finished product is a colourless, clear liquid in an amber glass pump spray containing *Allium cepa* in a final dilution of 6 X, *Drosera rotundifolia* in a final dilution of 6 X and *Gelsemium sempervirens* in a final dilution of 6 X. The excipients used to manufacture the homeopathic medicinal product are purified water and ethanol. Both excipients are considered to be compatible with the homeopathic stocks and do not influence the performance of the product.

Both excipients used comply with their respective Ph. Eur. monograph. Certificates of Analysis for the excipients have been provided by the suppliers.

Manufacture

A flow diagram outlining the various stages of the manufacturing process and the in-process controls is provided. The critical steps of the process have been validated and 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 homeopathic medicinal product, demonstrating little inter-batch variation.

Container Closure System

The product is presented in a 20ml, Type I glass, amber bottle with a plastic atomiser closer, covered with a plastic dust cap. Each metered dose contains 0.08 – 0.13ml of spray and each vial contains approximately 200 metered doses. 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 when stored in an unopened container, reduced to 6 months once the container is first opened. This is appropriate when the storage precautions “Do not store above 25°C” 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

SAFETY OVERVIEW

The applicant has presented an overview of the safety of the three homeopathic stocks and the combination of stocks in the finished product and concluded that it is highly unlikely that they will exert any acute or chronic toxic effects or any genotoxic effects.

The applicant has not provided any new safety data in support of their application. This is justified on the basis that the product is derived from a stocks present in licensed medicinal products. The applicant has provided details of Homeopathic Registrations (HR) and Product Licences of Right (PLR) containing the stocks. The information provided is satisfactory.

As this product contains the excipient ethanol, appropriate warnings are included in the SmPC.

CONCLUSION

There are no objections to the granting of a Homeopathic Marketing Authorisation from a safety point of view.

CLINICAL ASSESSMENT (NON SAFETY)

LEGAL STATUS

Allium cepa, *Drosera rotundifolia* and *Gelsemium sempervirens* were already General Sales List (GSL) ingredients prior to the submission of this application. Therefore, GSL has been granted for this product.

INDICATION

The applicant has proposed the following indication:

“Weleda Cold Relief Oromucosal Spray is a homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of the common cold, cough associated with the common cold, and related flu-like symptoms.”

This indication is acceptable.

POSODOLOGY AND METHOD OF ADMINISTRATION

The applicant has proposed the following

“Adults, elderly and children over 12 years:

- for oral use only
- hold the spray upright, a few centimetres from the mouth
- open your mouth, and apply one or two metered sprays into the mouth up to 3 times daily. Change the site of application each time to minimise any potential irritation
- administration to children aged 12 to 18 years should be supervised by an adult
- do not swallow
- ideally doses should be taken half an hour before or half an hour after food or drink
- if symptoms worsen or persist after 7 days of taking this product, consult a doctor or qualified healthcare practitioner

Weleda Cold Relief Oromucosal Spray is not for use in children below 12 years of age.”

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.

Justification for homeopathic use of the stocks

The applicant has provided *Materia medica* references, published clinical studies and other bibliographic evidence to support the traditional homeopathic use of the individual homeopathic stocks in Weleda Cold Relief Oromucosal Spray in the indications sought.

Justification for homeopathic use of the combination

Weleda Cold Relief Oromucosal Spray is a novel combination of three well-known homeopathic stocks in an oromucosal spray. The Applicant considers that a combination of *Allium cepa*, *Drosera* and *Gelsemium* according to the individual clinical uses, historical provings and current published material would be considered appropriate for the proposed indication for Weleda Cold Relief. To support the clinical safety of the combination, the Applicant reported that JH Clarke cites no incompatibility with the combination of *Allium cepa*, *Drosera* and *Gelsemium*

Justification for the homeopathic potency

Weleda Cold Relief Oromucosal Spray contains 6 X homeopathic dilutions of *Allium cepa*, *Drosera* and *Gelsemium*. The Applicant has stated that 6X is a common dilution which traditionally allows for frequent dosing in acute conditions. General literature references have been provided supporting the choice of low potencies within the homeopathic tradition (3X to 6C), which are considered to be shorter acting and, when used frequently in combination, can offer symptomatic relief in acute conditions.

Justification for the pharmaceutical form

The Applicant has stated that Weleda Cold Relief Oromucosal Spray is a modern, easy to use delivery system for a combination of liquid homeopathic preparations. The oromucosal spray is considered to aid convenience of administration, rather than three separate remedies, and is easy to carry around and for frequent administration.

Justification to demonstrate UK homeopathic practitioners' support

Statements from UK medical homeopathic practitioners endorsing the use of the product within the indications sought have been provided. The statements are satisfactory.

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.

WELEDA COLD RELIEF OROMUCOSAL SPRAY

NR 00298/0274

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received an application under the Homeopathic National Rules Scheme (Article 16.2) on 28 June 2010
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 25 August 2010
3	Following assessment of the application and a meeting of the Advisory Board on the Registration of Homeopathic products (ABRH) on 19 October 2010, the MHRA requested further information relating to the dossier on 10 November 2010
4	The applicant responded to the MHRA's request, providing further information on the dossier on 17 November 2011
5	Following assessment of the response the MHRA requested further information relating to the dossier on 21 January 2013
6	The applicant responded to the MHRA's request, providing further information on the dossier on 24 April 2013
7	A National Rules Marketing Authorisation was granted on 6 August 2013

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Weleda Cold Relief Oromucosal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered spray contains:

Allium cepa 6X

Drosera rotundifolia 6X

Gelsemium sempervirens 6X

Excipient with known effect:

16.6% w/w Ethanol (See Section 4.4 'Special warnings and precautions for use.')

Each metered spray contains 12.9mg to 20.9mg of ethanol

3 PHARMACEUTICAL FORM

Oromucosal spray, colourless, clear liquid in an amber glass pump spray.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Weleda Cold Relief Oromucosal Spray is a homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of the common cold, cough associated with the common cold, and related flu-like symptoms.

4.2 Posology and method of administration

Adults, elderly and children over 12 years:

- for oral use only
- hold the spray upright, a few centimetres from the mouth
- open your mouth, and apply one or two metered sprays into the mouth up to 3 times daily. Change the site of application each time to minimise any potential irritation
- administration to children aged 12 to 18 years should be supervised by an adult
- do not swallow
- ideally doses should be taken half an hour before or half an hour after food or drink
- if symptoms worsen or persist after 7 days of taking this product, consult a doctor or qualified healthcare practitioner

Weleda Cold Relief Oromucosal Spray is not for use in children below 12 years of age.

4.3 Contraindications

Hypersensitivity to any of the active ingredients or ethanol.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If fever develops or if symptoms worsen or persist after 7 days of taking this product, consult a doctor or qualified healthcare practitioner

The formulation of this product is not suitable for use in children under 12 years of age.

Do not spray into the throat or eyes.

The effects of alcohol may be increased and therefore concurrent use should be avoided

This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per dose

If fever is experienced or if there is a history of asthma or other chronic respiratory conditions, consult a doctor or qualified healthcare practitioner before starting to take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

This medicinal product contains small amounts of ethanol (alcohol), therefore concurrent use should be avoided with other medication known to interact with alcohol e.g. metronidazole and disulfiram.

4.6 Fertility, pregnancy and lactation

There is no evidence of the safety of the product in human pregnancy and lactation. The use of the product during pregnancy and lactation should be avoided unless under the guidance of a medical practitioner.

This product contains small amounts of alcohol.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

This product contains small amounts of alcohol (see section 2)

4.8 Undesirable effects

There are no reports of adverse effects.

If adverse effects occur a doctor or pharmacist 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 balance 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

No studies have been performed. Symptomatic and supportive measures should be taken as appropriate.

The amount of alcohol per metered spray is 0.016 – 0.027ml, 12.9-20.9mg of ethanol.

The amount of alcohol in a full bottle (20ml) is 4.09ml/3.23g ethanol.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic dosage (ATC code) Homeopathic preparations – V03AX

5.2 Pharmacokinetic properties

Not applicable to product of this type

5.3 Preclinical safety data

None available

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water

Ethanol

6.2 Incompatibilities

None known

6.3 Shelf life

5 years

Discard 6 months after first opening.

6.4 Special precautions for storage

Do not store above 25°C

Discard 6 months after first opening

Store in the original package

6.5 Nature and contents of container

20ml Type I glass amber bottle with a plastic atomiser closer, covered with a plastic dust cap.

Each metered dose contains 0.08 – 0.13ml of Spray

Each vial contains approximately 200 metered doses

6.6 Special precautions for disposal

There are no special precautions.

- 7 MARKETING AUTHORISATION HOLDER**
Weleda (UK) Ltd
Heanor Road, Ilkeston
Derbyshire. DE7 8DR
0115 944 8200
0115 944 8210
info@weleda.co.uk
- 8 MARKETING AUTHORISATION NUMBER(S)**
NR 00298/0274
- 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

WELEDA COLD RELIEF OROMUCOSAL SPRAY



Oromucosal spray containing: Allium cepa 6X, Drosera rotundifolia 6X, Gelsemium sempervirens 6X.

WELEDA

HOMEOPATHIC MEDICINAL PRODUCT

Read this leaflet carefully because it contains important information for you. Keep this leaflet as you may need to read it again.

In this leaflet:

1. What the product is and what it is used for
2. Before taking this product
3. How to use this product
4. Possible side effects
5. How to store this product
6. Further information

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

Weleda Cold Relief Oromucosal Spray is a homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of the common cold, cough associated with the common cold, and related flu-like symptoms.

2. Before taking this product

- **Do not take this product if:**
 - you are allergic to any of the active ingredients or ethanol (alcohol) - see section 6
 - you are under 12 years of age
- **Consult your Doctor or Pharmacist if:**
 - you are taking other prescription medicines
 - you are pregnant or breastfeeding
- **Special warnings and precautions for use:**
 - if fever develops or if symptoms worsen or persist after 7 days of taking this product, consult a doctor or qualified healthcare practitioner
 - if you have a fever, currently have asthma or another chronic respiratory condition or a history of these conditions, consult your doctor or qualified healthcare practitioner before taking this medicine.
 - the formulation of this product is not suitable for use in children under 12 years of age
 - this medicinal product contains small amounts of ethanol (alcohol), less than 100mg per dose, therefore it should not be used with medication known to interact with alcohol e.g. metronidazole and disulfiram
 - the effects of alcohol may be increased and therefore concurrent use should be avoided
- **Driving and using machines**

No studies have been carried out on the effects on the ability to drive or operate machines. If affected do not drive or operate machines. This product contains a small quantity of ethanol (alcohol).

3. How to use this product

Before using this product for the first time:

Your Weleda Cold Relief Oromucosal Spray has a dust cap which protects the nozzle and keeps it clean. Remember to take it off to use the spray. Before you start a new bottle, or if you have not used the spray for a few days or more, press the pump down several times (away from you) until you get a fine spray.

Adults, elderly and children over the age of 12 years:

- for oral use only
- hold the spray upright, a few centimetres from the mouth
- open your mouth and apply 1 or 2 metered sprays into the mouth up to 3 times daily. Change the site of application each time to minimise any potential irritation
- administration to children aged 12 to 18 years should be supervised by an adult
- do not swallow
- ideally doses should be taken half an hour before or half an hour after food or drink
- do not spray into the throat or eyes
- if symptoms worsen or persist after 7 days of taking this product, consult a doctor or qualified healthcare practitioner

Weleda Cold Relief Oromucosal Spray is not for use in children under the age of 12 years.

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Do not exceed the stated dose

- if you miss a dose of Weleda Cold Relief Oromucosal Spray just take the next dose as usual.

Overdose

- if you take more of Weleda Cold Relief Oromucosal Spray than you should, do not worry, taking too many doses is not known to be harmful. However if you feel unwell, consult your doctor.

4. Possible side-effects

There are no known side-effects when using Weleda Cold Relief Oromucosal Spray. If you notice any side-effects or if symptoms worsen or persist after 7 days of taking this product, consult a doctor or qualified healthcare practitioner.

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).

5. How to store this product

- keep out of the reach and sight of children
- do not store above 25°C
- discard 6 months after first opening
- keep the container in the outer carton
- do not use after the expiry date on the carton and label
- medicine should not be disposed of via wastewater or household waste. Return any unused medicine to your pharmacist for safe disposal

6. Further Information

Each metered spray contains the following ingredients: Allium cepa 6X, Drosera rotundifolia 6X, Gelsemium sempervirens 6X.

Other ingredients: Purified Water, Ethanol 16.6% w/w.

Pack Description: This product is a colourless, clear liquid packed in a 20ml glass amber bottle incorporating a plastic spray nozzle which is covered with a plastic dust cap.

Each 20ml spray bottle contains approximately 200 metered doses, each dose consisting of 0.08 - 0.13ml of spray.

National Rules holder and manufacturer: Weleda Cold Relief Oromucosal Spray is manufactured and marketed by Weleda UK Ltd., Heanor Road, Ilkeston, Derbyshire DE7 8DR.

National Rules authorisation number NR 00298/0274.

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 Cold Relief Oromucosal Spray.

Reference number NR 00298/0274.

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

For further information concerning homeopathic medicines contact: The Faculty of Homeopathy, Hahnemann House, 29 Park Street West, LUTON LU1 3BE.

For further information on anthroposophic medicine contact: PAFAM, 33 Franche Road, Wolverley, KIDDERMINSTER, Worcester, DY11 5TP.

Weleda Cold Relief Oromucosal Spray contains a combination of Homeopathic medicinal remedies, rhythmically prepared in Anthroposophic tradition.

LABELLING

