#### PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

#### 1. NAME OF THE MEDICINAL PRODUCT

Nelsons Calendula Cream

# 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each gram of cream contains: 9.0% v/w tincture of Calendula flowers (Calendula officinalis L.) (1:10) Extraction solvent: Ethanol 0.3 % v/w

#### 3. LIST OF EXCIPIENTS

Purified water

Arlacel 170 (Glyceryl Stearate and PEG-100 Stearate)

Apricot kernel oil

Theobroma oil (Cocoa butter)

Glycerol

Polawax GP 200 (Cetearyl alcohol, PEG-20 Stearate)

Cetostearyl alcohol

Cetyl palmitate

Glyceryl monocaprylate

Methyl parahydroxybenzoate E218

Propyl parahydroxybenzoate E216

Fragrance (Compo Cos: benzyl benzoate; propanol -oxybis; benzoate, 2,4-dihydro-3,6-dimethyl-, methyl; oils, oakmoss-resinoid)

## 4. PHARMACEUTICAL FORM AND CONTENTS

Cream

30g or 50g

### 5. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical use only

# 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

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

#### 7. OTHER SPECIAL WARNING(S), IF NECESSARY

If symptoms worsen or if signs of a skin infection are observed or if symptoms persist after using the product for 1 week, a doctor or a qualified healthcare practitioner should be consulted.

Warnings: Do not use this product: if you are pregnant or breast feeding, if you are allergic to any of the ingredients or to plants of the Asteracea (Compositae) family, if you are under 6 years of age

Important information about some of the ingredients.

Cetearyl alcohol may cause skin reactions (e.g. contact dermatitis).

Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) in this medicine may cause allergic reactions (possibly delayed).

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## 8. EXPIRY DATE

EXP

Do not use after the expiry date

#### 9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

# 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

### 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

A Nelson & Co Limited 5-9 Endeavour Way Wimbledon London, England SW19 8UH

## 12. MARKETING AUTHORISATION NUMBER(S)

THR 01175/0400

#### 13. BATCH NUMBER

Lot No

# 14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

#### 15. INSTRUCTIONS ON USE

Directions

Check that the tube seal is not broken before first use.

Pierce tube seal with point in top of cap before first use.

Wash hands before and after use.

Adults, the elderly and children over 6 years: Apply liberally to affected area 4 times a day as required.

Not recommended for use in children under 6 years of age.

## 16. INFORMATION IN BRAILLE

NELSONS CALENDULA CREAM

#### 17. OTHERS

A traditional herbal medicinal product used for the symptomatic relief of sore and rough skin, based on traditional use only.

Possible side effects: This product may cause skin sensitization.

If this or any other side effect occurs, consult your doctor or qualified healthcare practitioner

#### Making medicines safer:

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcar. Alternatively you can get a paper Yellow Card form from your doctor's surgery or a pharmacyor call freephone 0808 100 3352 (available 10 am - 2 pm Monday to Friday)

THR Certification Mark

Natural care since 1860

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#### PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

**Tube** 

#### 1. NAME OF THE MEDICINAL PRODUCT

Nelsons Calendula Cream

# 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each gram of cream contains: 9.0% v/w tincture of Calendula flowers (Calendula officinalis L.) (1:10) Extraction solvent: Ethanol 0.3 % v/v

## 3. LIST OF EXCIPIENTS

Purified water

Arlacel 170 (Glyceryl Stearate and PEG-100 Stearate)

Apricot kernel oil

Theobroma oil (Cocoa butter)

Glycerol

Polawax GP 200 (Cetearyl alcohol, PEG-20 Stearate)

Cetostearyl alcohol

Cetyl palmitate

Glyceryl monocaprylate

Methyl parahydroxybenzoate E218

Propyl parahydroxybenzoate E216

Fragrance NB01 (Alban Muller International, COMPO COS)

## 4. PHARMACEUTICAL FORM AND CONTENTS

Cream

30g or 50g

### 5. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical use only

# 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

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

## 7. OTHER SPECIAL WARNING(S), IF NECESSARY

If symptoms worsen or if signs of a skin infection are observed or if symptoms persist after using the product for for 1 week, a doctor or a qualified healthcare practitioner should be consulted.

Warnings: Do not use this product: if you are pregnant or breast feeding, if you are allergic to any of the ingredients or to plants of the Asteracea (Compositae) family, if you are under 6 years of age Important information about some

of the ingredients. Cetearyl alcohol may cause skin reactions (e.g. contact dermatitis). Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) in this medicine may cause allergic reactions (possibly delayed).

#### 8. EXPIRY DATE

# 9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

# 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

# 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

A Nelson & Co Limited 5-9 Endeavour Way Wimbledon London, England SW19 8UH

# 12. MARKETING AUTHORISATION NUMBER(S)

THR 01175/0400

## 13. BATCH NUMBER<, DONATION AND PRODUCT CODES>

Lot No

# 14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

# 15. INSTRUCTIONS ON USE

Directions

Check that the tube seal is not broken before first use.

Pierce tube seal with point in top of cap before first use.

Wash hands before and after use.

Adults, the elderly and children over 6 years: Apply liberally to affected area 4 times a day as required.

## 16. INFORMATION IN BRAILLE

#### 17. OTHERS

A traditional herbal medicinal product used for the symptomatic relief of sore and rough skin, based on traditional use only.