

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Dulbalm Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ethyl Nicotinate	1%
Methyl Nicotinate	1%
Benzyl Nicotinate	1%
Glycol Salicylate	2%
Capsicum Oleoresin	0.01%

Excipient(s) with known effect:

Polysorbate 80

For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Cream

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

External application for the symptomatic treatment of muscle stiffness, muscular rheumatism, lumbago, sciatica, fibrositis, sprains and chilblains.

### 4.2. Posology and method of administration

Apply externally with gentle massage 2 - 3 times daily, avoiding broken or inflamed skin.

DO NOT APPLY TO CHILDREN UNDER 6 YEARS OF AGE.

#### **4.3. Contra-indications**

Known sensitivity to any of the ingredients.  
Do not apply to children less than six years old.

#### **4.4 Special warnings and precautions for use**

Do not apply to broken or tender skin.  
Application on mucous membranes should be avoided.  
Discontinue if rash develops.  
Not for use with occlusive dressings.  
Topical application may result in systemic effects, including asthma.  
Patients should be advised against excessive exposure of areas treated to sunlight, in order to avoid possibility of photosensitivity.  
Keep away from eyes.  
Wash hands after use.

#### **4.5. Interactions with other medicinal products and other forms of interaction**

None known.

#### **4.6. Fertility, pregnancy and lactation**

As with most medicines, use in pregnancy or breastfeeding should be avoided.

#### **4.7. Effects on ability to drive and use machines**

Not applicable.

#### **4.8 Undesirable effects**

Photosensitivity and application site 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](http://www.mhra.gov.uk/yellowcard) or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

#### **4.9. Overdose**

Not applicable.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

All the active ingredients in Dulbalm Cream are topical vasodilators with rubefacient activity.

### **5.2. Pharmacokinetic properties**

External application of Dulbalm Cream to intact skin results in negligible systemic absorption.

### **5.3. Preclinical safety data**

Not applicable.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Emulsifying Wax, White Soft Paraffin, Polysorbate 80, Cineole, Purified Water.

### **6.2. Incompatibilities**

None known.

### **6.3. Shelf life**

36 months.

**6.4 Special precautions for storage**

Store below 25°C.

Keep this medicine out of the sight and reach of children.

**6.5 Nature and contents of container**

Aluminium tube, 25g.

**6.6 Special precautions for disposal**

No special handling is required.

**7 MARKETING AUTHORISATION HOLDER**

Norma Chemicals Ltd.

51-53 Stert Street

Abingdon

Oxfordshire OX14 3JF

United Kingdom

**8. MARKETING AUTHORISATION NUMBER**

PL 00386/5007R

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

29 December 1983 / 28 February 1995

**10 DATE OF REVISION OF THE TEXT**

15/05/2025