

**EMCREM CREAM**  
**(White soft paraffin 15.0% w/w, Liquid paraffin 6.0% w/w)**  
**PL 19876/0013**

**UKPAR**

**TABLE OF CONTENTS**

Lay Summary	Page 2
Scientific discussion	Page 3
Steps taken for assessment	Page 11
Steps taken after authorisation – summary	
Summary of Product Characteristics	Page 12
Product Information Leaflet	Page 14
Labelling	Page 18

**EMCREM CREAM**  
**(White soft paraffin 15% w/w, Liquid paraffin 6% w/w)**  
**PL 19876/0013**

**LAY SUMMARY**

On 16 March 2011, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Centrapharm Limited a Marketing Authorisation (licence) for the medicinal product Emcrem Cream (PL 19876/0013). This is a General Sales List (GSL) medicine used to treat red, inflamed, damaged, dry or chapped skin in adults and children, and to protect raw skin areas. Emcrem Cream can be applied before having a bath to prevent the skin from drying any further, in patients with dry skin who suffer from the skin condition eczema. Emcrem Cream can also be used during or after treatment with topical steroid creams, gels or ointments.

Emcrem Cream is an emollient, moisturising and protective cream. It helps to smooth, soothe and hydrate the skin and prevent moisture loss.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Emcrem Cream outweigh the risks; hence a Marketing Authorisation has been granted.

**EMCREM CREAM**  
**(White soft paraffin 15.0% w/w, Liquid paraffin 6.0% w/w)**  
**PL 19876/0013**

**SCIENTIFIC DISCUSSION**

**TABLE OF CONTENTS**

<b>Introduction</b>	<b>Page 4</b>
<b>Pharmaceutical assessment</b>	<b>Page 5</b>
<b>Non-clinical assessment</b>	<b>Page 8</b>
<b>Clinical assessment</b>	<b>Page 9</b>
<b>Overall conclusions and risk assessment</b>	<b>Page 10</b>

## **INTRODUCTION**

Based on the review of the data on quality, safety and efficacy, the MHRA granted Centrapharm Limited a Marketing Authorisation for the medicinal product Emcrem Cream (PL 19876/0013) on 16 March 2011. This is a General Sales List (GSL) medicine recommended for the symptomatic treatment of red inflamed, damaged, dry or chapped skin, the protection of raw skin areas and as a pre-bathing emollient for dry/eczematous skin to alleviate drying. Emcrem Cream is an emollient, moisturising and protective cream for use following treatment with topical steroids or during such treatment. It may also be used as a diluent for topical steroids.

The application was submitted according to Article 10a of Directive 2001/83/EC, as amended, claiming to be a 'well established use' application.

Emcrem Cream contains the active ingredients white soft paraffin (15.0% w/w) and liquid paraffin (6.0% w/w) which provide emollient, moisturising action on dry or chapped skin.

No new non-clinical or clinical studies were conducted for this application, which is acceptable given that this was a bibliographic application for a product containing active ingredients of well-established use.

No new or unexpected safety concerns were raised during the assessment of this application and it was, therefore, judged that the benefits of using Emcrem Cream outweigh the risks; hence a Marketing Authorisation has been granted.

## **PHARMACEUTICAL ASSESSMENT**

### **ACTIVE SUBSTANCE: WHITE SOFT PARAFFIN**

INN:	White soft paraffin
Appearance:	White or almost white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted.
Solubility:	Practically insoluble in water, slightly soluble in methylene chloride, practically insoluble in ethanol (96%) and glycerol.

White soft paraffin is the subject of a European Pharmacopoeia monograph.

Manufacture of the active substance from the designated starting materials has been adequately described, and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant Certificates of Analysis.

An appropriate specification is provided for the active substance. The analytical methods used are as stated in the monograph. Batch analysis data are provided and comply with the proposed specification.

The primary packaging complies with current guidelines concerning articles intended to come into contact with foodstuff.

No stability data have been presented on the basis that this is a pharmacopoeial product, which is acceptable.

### **ACTIVE SUBSTANCE: LIQUID PARAFFIN**

INN:	Liquid paraffin
Appearance:	A transparent, colourless, oily liquid, free from fluorescence by daylight.
Solubility:	Practically insoluble in water, slightly soluble in ethanol (96%), miscible with hydrocarbons.

Liquid paraffin is the subject of a European Pharmacopoeia monograph

Manufacture of the active substance from the designated raw materials has been adequately described, and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant Certificates of Analysis.

An appropriate specification is provided for the active substance. The analytical methods used are as stated in the monograph. Batch analysis data are provided and comply with the proposed specification.

The primary packaging complies with current guidelines concerning articles intended to come into contact with foodstuff.

No stability data have been presented on the basis that this is a pharmacopoeial product, which is acceptable.

## **MEDICINAL PRODUCT**

### **Other Ingredients**

Other ingredients consist of the pharmaceutical excipients, namely macrogol cetostearyl ether, cetostearyl alcohol, chlorocresol, anhydrous sodium dihydrogen phosphate, dilute phosphoric acid and purified water.

All excipients comply with their respective European Pharmacopoeia monograph. Satisfactory Certificates of Analysis have been provided for all excipients.

None of the excipients contain materials of animal or human origin. No genetically modified organisms (GMO) have been used in the preparation of these excipients.

### **Pharmaceutical Development**

The objective of the development programme was to formulate a safe, efficacious, stable product containing the active ingredients white soft paraffin 15.0% w/w and liquid paraffin 6.0% w/w.

Suitable pharmaceutical development data have been provided for this application.

### **Manufacturing Process**

A description and flow-chart of the manufacturing method have been provided.

In-process controls are satisfactory based on process validation data and controls on the finished product. Process validation on batches has been provided.

### **Finished Product Specification**

The finished product specification proposed is satisfactory. Test methods have been described and have been adequately validated. Batch data have been provided and comply with the release specifications.

### **Container Closure System**

The finished product is packaged in either:

1. 50g aluminium epoxyphenolic-lined tubes with polypropylene screw caps
2. 500g polypropylene plastic pump packs with polypropylene/ high density polyethylene (HDPE) dip tubes and caps, or
3. 500g polypropylene jars (containers) with polypropylene dispenser heads and covers, the pump system consists of a polyethylene follower plate, a polypropylene pump cylinder, a polyethylene piston with a glass and a polyethylene valve.

Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging is controlled to current European Pharmacopoeia standards and complies with guidelines concerning articles intended to come into contact with food products and the guidelines concerning plastic packaging materials for pharmaceutical use.

**Stability of the Product**

Stability studies were performed in accordance with current guidelines on batches of finished product packed in the packaging proposed for marketing. The data from these studies support a shelf-life of 24 months, with the storage conditions, "Do not store above 25°C."

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

**Bioequivalence/Bioavailability**

A bioequivalence study was not necessary to support this type of application.

**Summary of Product Characteristics (SmPC), Product Information Leaflets (PILs) and Labelling**

The SmPC, PILs and labelling are pharmaceutically satisfactory.

Package leaflets have 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, as amended. The results indicate that the package leaflets are 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.

**MAA Form**

The MAA form is satisfactory.

**Expert Report**

The pharmaceutical expert report is written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

**Conclusion**

The grant of a Marketing Authorisation is recommended.

## **NON-CLINICAL ASSESSMENT**

### **PHARMACODYNAMICS, PHARMACOKINETICS AND TOXICOLOGY**

No new non-clinical data were submitted, which is acceptable given that this was a bibliographic application for a product containing active substances of well-established use.

### **NON-CLINICAL EXPERT REPORT**

The non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the non-clinical aspects of the dossier.

### **CONCLUSION**

The grant of a Marketing Authorisation is recommended.



## **CLINICAL ASSESSMENT**

### **CLINICAL PHARMACOLOGY**

No new clinical pharmacology data were submitted or required for this application.

### **EFFICACY**

No new efficacy data were submitted or required for this application.

### **SAFETY**

No new safety data were submitted or required for this application. The applicant has provided an acceptable safety review from the literature. No new safety issues have been raised from this application.

### **PHARMACOVIGILANCE SYSTEM AND RISK MANAGEMENT PLAN**

The Pharmacovigilance System, as described by the applicant, fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

### **SUMMARY OF PRODUCT CHARACTERISTICS (SmPC), PRODUCT FORMATION LEAFLETS (PILs) AND LABELS**

The SmPC, PILs and labels are medically acceptable.

### **CLINICAL EXPERT REPORT**

The clinical expert report has been written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.

### **CONCLUSION**

The grant of a Marketing Authorisation is recommended.

## OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

### QUALITY

The important quality characteristics of Emcrem Cream are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit-risk balance.

### NON-CLINICAL

No new non-clinical data were submitted and none were required for this type of application. A non-clinical overview has been provided by an appropriately qualified person and consists of a review of the published literature.

### EFFICACY

No new data were submitted and none were required for this type of application.

The published literature supports the efficacy of this product in the proposed indication. This product is an emollient, moisturising and protective cream for use following treatment with topical steroids or during such treatment. It may also be used as a diluent for topical steroids. Emcrem Cream is recommended for the symptomatic treatment of red inflamed, damaged, dry or chapped skin, the protection of raw skin areas and as a pre-bathing emollient for dry/eczematous skin to alleviate drying. The efficacy of white soft paraffin and liquid paraffin is well-known. The presented evidence for well-established use of the active substances is sufficient.

### SAFETY

The safety profiles of white soft paraffin and liquid paraffin are well-known. The literature review identified no new or unexpected safety issues or concerns

### PRODUCT LITERATURE

The approved SmPC is satisfactory. The PILs and labelling texts are satisfactory, and consistent with the approved SmPC.

### BENEFIT-RISK ASSESSMENT

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. White soft paraffin and liquid paraffin are well-known active substances. Extensive clinical experience with white soft paraffin and liquid paraffin is considered to have demonstrated the therapeutic value of the product. The benefit-risk is, therefore, considered to be positive.

**EMCREM CREAM**  
**(White soft paraffin 15.0% w/w, Liquid paraffin 6.0% w/w)**

**PL 19876/0013**

**STEPS TAKEN FOR ASSESSMENT**

- 1 The MHRA received the marketing authorisation application on 14 October 2003.
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 17 November 2003.
- 3 Following assessment of the application the MHRA requested further information relating to the clinical dossier on 12 February 2004, and the quality dossier on 27 April 2005, 02 August 2006, 29 January 2010, 01 October 2010, 07 October 2010, 01 November 2010 and 15 March 2011.
- 4 The applicant responded to the MHRA's requests, providing further information on the clinical dossier on 25 May 2004, and on the quality dossier on 09 July 2004, 24 April 2008, 05 January 2010, 12 January 2010, 22 April 2010, 08 July 2010, 07 October 2010, 16 November 2010, 16 December 2010 and 15 March 2011.
- 5 The application was determined and granted on 16 March 2011.

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Emcrem Cream

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Active substances:**

White Soft Paraffin 15.0% w/w

Liquid Paraffin 6.0% w/w

Excipient(s): Cetostearyl alcohol (7.2% w/w), chlorocresol (0.1% w/w)

For a full list of excipients, see section 6.1

### **3 PHARMACEUTICAL FORM**

Cream

A smooth, white to off white cream.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Emcrem is an emollient, moisturising and protective cream for the follow-up treatment with topical steroids or in spacing such treatment. It may also be used as diluent for topical steroids. Emcrem is recommended for the symptomatic treatment of red inflamed, damaged, dry or chapped skin, the protection of raw skin areas and as a pre-bathing emollient for dry/eczematous skin to alleviate drying areas.

#### **4.2 Posology and method of administration**

For topical use.

##### Adults, Elderly and Children:

The cream should be applied to the dry skin areas as often as is required and rubbed well into the skin.

#### **4.3 Contraindications**

There are no absolute contraindications to the use of the cream other than hypersensitivity to any of the ingredients.

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

Some of the ingredients in the cream may cause a reaction:-

Cetostearyl alcohol – may cause local skin reactions (e.g. contact dermatitis).

Chlorocresol – may cause an allergic reaction.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None stated

#### **4.6 Pregnancy and lactation**

None stated

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

None stated

#### **4.8 Undesirable effects**

Skin reactions including pruritus, rash, erythema, skin exfoliation, burning sensation, hypersensitivity, pain, dry skin and dermatitis have been reported with product use.

#### **4.9 Overdose**

None stated

**5 PHARMACOLOGICAL PROPERTIES****5.1 Pharmacodynamic properties**

ATC Code: D02A

Emollients and Protectives

The ingredients provide emollient, moisturising action on dry or chapped skin.

**5.2 Pharmacokinetic properties**

Not applicable due to topical administration and direct action on the skin.

**5.3 Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

**6 PHARMACEUTICAL PARTICULARS****6.1 List of excipients**

Macrogol Cetostearyl Ether

Cetostearyl Alcohol

Chlorocresol

Anhydrous Sodium Dihydrogen Phosphate

Dilute Phosphoric acid

Purified water

**6.2 Incompatibilities**

None Known

**6.3 Shelf life**

24 Months

**6.4 Special precautions for storage**

Do not store above 25°C

**6.5 Nature and contents of container**

50g aluminium epoxy phenolic lined tube with polypropylene screw cap.

500g polypropylene plastic pump pack with polypropylene/HDPE dip tube and cap, or

500g polypropylene jar (container) with a polypropylene dispenser head and cover, the pump system consists of a polyethylene follower plate, a polypropylene pump cylinder, a polyethylene piston with a glass and a polyethylene valve.

**6.6 Special precautions for disposal**

Not Applicable

**7 MARKETING AUTHORISATION HOLDER**

Centrapharm Ltd

Finch House

28-30 Wolverhampton Street

Dudley

West Midlands

DY1 1DB

United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 19876/0013

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

16/03/2011

**10 DATE OF REVISION OF THE TEXT**

16/03/2011

## PRODUCT INFORMATION LEAFLET

### Package leaflet: Information for the user

# Emcrem Cream

White Soft Paraffin 15% w/w  
Liquid Paraffin 6% w/w

**Please read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. Nevertheless, you still need to use Emcrem carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.
- If any of the side effects become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

[1]

### 5. HOW TO STORE EMCREM

**Keep out of the reach and sight of children.**

Do not use Emcrem after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month. Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6. FURTHER INFORMATION

**What Emcrem contains:**

The active ingredients are white soft paraffin 15%w/w and liquid paraffin 6%w/w.

The other ingredients are chlorocresol, macrogol cetostearyl ether, cetostearyl alcohol, dilute phosphoric acid, sodium dihydrogen phosphate and purified water.

[6]

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Emcrem can have side effects although not everybody may get them. If your symptoms persist or the condition worsens, stop using the cream and consult your doctor or pharmacist.

Skin reactions including itching, rash, redness, peeling, burning, pain, dryness and skin inflammation (dermatitis) have been reported. If you are worried by this or any other effects, you should tell your doctor or pharmacist.

If any of the side effects become serious or if you experience any side-effects not mentioned in this leaflet, please tell your doctor or pharmacist.

[5]

### In this leaflet:

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

### 1. WHAT EMCREM IS AND WHAT IT IS USED FOR

Emcrem is an emollient, moisturising and protective cream. It helps to smooth, soothe and hydrate the skin and prevent moisture loss. Emcrem is used to treat red, inflamed, damaged, dry or chapped skin in adults and children, and to protect raw skin areas. If you suffer from a skin condition called eczema and your skin is dry, the cream can be applied before having a bath to prevent your skin from drying any further.

Emcrem can also be used during or after treatment with topical steroid creams, gels or ointments.

[2]

**2. BEFORE YOU USE EMCREM**

**Do not use Emcrem:**

If you are hypersensitive (allergic) to white soft paraffin, liquid paraffin or any of the other ingredients of Emcrem. Tell your doctor so that he or she can give you another medicine.

**Using other medicines:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

**Pregnancy and breast-feeding:**

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines:**

Emcrem has no influence on the ability to drive and use machines.

**Important information about some of the ingredients of Emcrem:**

Some of the ingredients in your cream may cause a reaction such as cetostearyl alcohol which may cause a local skin reaction (e.g. contact dermatitis) and chlorocresol which may cause an allergic reaction.

[3]

**3. HOW TO USE EMCREM**

Always use Emcrem exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor may have told you when and how often to use the cream and how long to use it for. If so, check the label to remind you what they said. The cream should be thinly applied to cover the affected area completely, massaging gently and thoroughly into the skin as often as is required.

If your condition worsens, or your symptoms persist beyond the period of treatment specified by your doctor, you should consult your doctor or pharmacist.

If you have the impression that the effect of Emcrem is too strong or too weak, talk to your doctor or pharmacist. Emcrem is for external use only.

**If you forget to use Emcrem:**

If you forget to use your cream at the right time, use the usual amount as soon as you remember, then carry on as before.

[4]

**What Emcrem looks like and contents of the pack:**

Emcrem is a smooth, white cream. It is available in a tube containing 50g and a pump dispenser containing 500g. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

The holder of the Marketing Authorisation is:  
**Centrapharm Ltd**  
Finch House, 28-30 Wolverhampton St.  
Dudley, West Midlands DY1 1DB  
United Kingdom

The manufacturer of Emcrem is  
**Bioglan AB**  
PO Box 50310, SE-202 13 Malmö,  
Sweden

**This leaflet was last approved  
October 2010**

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[7]

The active substances are white soft paraffin 15% and liquid paraffin 6% w/w.

**Also contains:**

Chlorocresol, macrogol cetostearyl ether, cetostearyl alcohol, dilute phosphoric acid, sodium dihydrogen phosphate, purified water.

**Read package leaflet before use.**

**For topical application:**

Apply a thin layer of cream and massage thoroughly into affected areas of skin as often as required or as advised by your doctor.

**Keep out of the reach and sight of children.**

FOR EXTERNAL USE ONLY

Do not store above 25°C

MA Holder

**Centrapharm Ltd**

Finch House, 28-30 Wolverhampton St.  
Dudley, West Midlands, DY1 1DB  
United Kingdom

PL 19876/0013



PULL HERE

DO NOT REMOVE

**Package leaflet: Information for the user**

# Emcrem Cream

White Soft Paraffin 15% w/w, Liquid Paraffin 6% w/w

**Please read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. Nevertheless, you still need to use Emcrem carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.
- If any of the side effects become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

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

**1. WHAT EMCREM IS AND WHAT IT IS USED FOR**

Emcrem is an emollient, moisturising and protective cream. It helps to smooth, soothe and hydrate the skin and prevent moisture loss.

Emcrem is used to treat red, inflamed, damaged, dry or chapped skin in adults and children, and to protect raw skin areas. If you suffer from a skin condition called eczema and your skin is dry, the cream can be applied before having a bath to prevent your skin from drying any further.

Emcrem can also be used during or after treatment with topical steroid creams, gels or ointments.

**2. BEFORE YOU USE EMCREM****Do not use Emcrem:**

If you are hypersensitive (allergic) to white soft paraffin, liquid paraffin or any of the other ingredients of Emcrem. Tell your doctor so that he or she can give you another medicine.

**Using other medicines:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

**Pregnancy and breast-feeding:**

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines:**

Emcrem has no influence on the ability to drive and use machines.

**Important information about some of the ingredients of Emcrem:**

Some of the ingredients in your cream may cause a reaction such as cetostearyl alcohol which may cause a local skin reaction (e.g. contact dermatitis) and chlorocresol which may cause an allergic reaction.



**3. HOW TO USE EMCREM**

Always use Emcrem exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor may have told you when and how often to use the cream and how long to use it for. If so, check the label to remind you what they said. The cream should be thinly applied to cover the affected area completely, massaging gently and thoroughly into the skin as often as is required. If your condition worsens, or your symptoms persist beyond the period of treatment specified by your doctor, you should consult your doctor or pharmacist.

If you have the impression that the effect of Emcrem is too strong or too weak, talk to your doctor or pharmacist. Emcrem is for external use only.

**If you forget to use Emcrem:**

If you forget to use your cream at the right time, use the usual amount as soon as you remember, then carry on as before.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Emcrem can have side effects although not everybody may get them. If your symptoms persist or the condition worsens, stop using the cream and consult your doctor or pharmacist. Skin reactions including itching, rash, redness, peeling, burning, pain, dryness and skin inflammation (dermatitis) have been reported. If you are worried by this or any other effects, you should tell your doctor or pharmacist.

If any of the side effects become serious or if you experience any side-effects not mentioned in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE EMCREM****Keep out of the reach and sight of children.**

Do not use Emcrem after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month. Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION****What Emcrem contains:**

The active ingredients are white soft paraffin 15%w/w and liquid paraffin 6%w/w.

The other ingredients are chlorocresol, macrogol cetostearyl ether, cetostearyl alcohol, dilute phosphoric acid, sodium dihydrogen phosphate and purified water.

**What Emcrem looks like and contents of the pack:**

Emcrem is a smooth, white cream. It is available in a tube containing 50g and a pump dispenser containing 500g. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

The holder of the Marketing Authorisation is:

**Centrapharm Ltd**, Finch House, 28-30 Wolverhampton Street, Dudley, West Midlands DY1 1DB, United Kingdom.

The manufacturer of Emcrem is:

**Bioglan AB**, PO Box 50310, SE-202 13 Malmö, Sweden.

**This leaflet was last approved October 2010**

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**LABELLING**

**Tube:**

# Emcrem Cream

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White Soft Paraffin 15% w/w  
Liquid Paraffin 6% w/w

The active substances are white soft paraffin 15% w/w and liquid paraffin 6% w/w.

**Also contains:** chlorocresol, macrogol cetostearyl ether, cetostearyl alcohol, dilute phosphoric acid, sodium dihydrogen phosphate, purified water.

MA Holder  
**Centrapharm Ltd**  
Finch House,  
28-30 Wolverhampton St.  
Dudley, West Midlands, DY1 1DB,  
United Kingdom

PL 19876 / 00013

50g

**For topical application:**  
Apply a thin layer of cream and massage thoroughly into affected areas of skin as often as required or as advised by your doctor.

**Read package leaflet before use.**

**Keep out of the reach and sight of children.**

FOR EXTERNAL USE ONLY

Do not store above 25°C

B.N: XXXXXXXXXX

EXP: XXXXXXXXXX

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**Label:**

# Emcrem Cream

---

White Soft Paraffin 15% w/w  
Liquid Paraffin 6% w/w

500g

PULL HERE

DO NOT REMOVE

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Apply a thin layer of cream and massage thoroughly into affected areas of skin as often as required or as advised by your doctor.

**Keep out of the reach and sight of children.**

FOR EXTERNAL USE ONLY

Do not store above 25°C

MA Holder  
**Centrapharm Ltd**  
Finch House, 28-30 Wolverhampton St.  
Dudley, West Midlands, DY1 1DB  
United Kingdom

PL 19876/0013

5060061550093

B.N: XXXXXXXXXX

EXP: XXXXXXXXXX

Carton:

