



Medicines & Healthcare products  
Regulatory Agency



## **Public Assessment Report**

### **UKPAR**

**Nurofen Joint & Back Pain Relief 5% Gel  
Nurofen Muscular Pain Relief Gel Pharmacy Only**

**Ibuprofen**

**UK Licence No: PL 00063/0706-0707**

**Reckitt Benckiser Healthcare (UK) Limited**

## **LAY SUMMARY**

### **Nurofen Joint & Back Pain Relief 5% Gel Nurofen Muscular Pain Relief Gel Pharmacy Only (ibuprofen)**

This is a summary of the Public Assessment Report (PAR) for Nurofen Joint & Back Pain Relief 5% Gel (PL 00063/0706) and Nurofen Muscular Pain Relief Gel Pharmacy Only (PL 00063/0707). It explains how Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only.

For practical information about using Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only patients should read the package leaflets or contact their doctor or pharmacist.

#### **What are Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only and what are they used for?**

These products contain the active ingredient ibuprofen. They are gels that are rubbed onto the skin to treat pain and reduce inflammation associated with backache, rheumatic and muscular pain, sprains, strains and sports injuries.

These medicines are identical to Ibuprofen 5% Gel (PL 10972/0045), which was first granted a Marketing Authorisation (Goldshield Pharmaceuticals) on 26 April 1996.

#### **How are Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only used?**

These products are for use on the skin only. Patients should squeeze 4 to 10 cm of gel from the tube and lightly rub into the affected area until it is absorbed. Patients should then wash their hands straight away. Patients should not apply more gel within four hours or apply it more than four times in 24 hours.

Nurofen Joint & Back Pain Relief 5% Gel is available in 15, 30, 35 or 50 g pack sizes and can be obtained from pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

Nurofen Muscular Pain Relief Gel Pharmacy Only is available in a 100 g pack size and can be obtained from a pharmacy without a prescription, but under the supervision of a pharmacist.

For further information on how Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only are used, refer to the package leaflets and Summaries of Product Characteristics available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

#### **How do Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only work?**

The active ingredient ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). They work by relieving pain and reducing inflammation.

#### **What benefits of Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only have been shown in studies?**

The application for Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only is considered to be identical to the previously authorised application for Ibuprofen 5% Gel (PL 10972/0045), with the same benefits and risks, so, no new studies have been provided for Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only.

The company referred to the data provided for the grant of the licence for Ibuprofen 5% Gel (PL 10972/0045) as a basis for the grant of identical licences for Nurofen Joint & Back Pain Relief 5% Gel (PL 00063/0706) and Nurofen Muscular Pain Relief Gel Pharmacy Only (PL 00063/0707).

### **What are the possible side effects from Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only?**

Like all medicines, these medicines can cause side effects, although not everybody gets them.

Nurofen Joint & Back Pain Relief 5% Gel (PL 00063/0706) and Nurofen Muscular Pain Relief Gel Pharmacy Only (PL 00063/0707) are considered to be identical to the previously authorised application for Ibuprofen 5% Gel (PL 10972/0045) with the same benefits and risks.

For a full list of all the side effects reported with these medicines see section 4 of the package leaflets, available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

### **Why are Nurofen Muscular Pain Relief Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only approved?**

No new or unexpected safety concerns arose from these applications. The MHRA, therefore, considered that the benefits of Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only outweigh their risks; and the grant of Marketing Authorisations (licences) was recommended.

### **What measures are being taken to ensure the safe and effective use of Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only?**

Safety information has been included in the Summaries of Product Characteristics and the package leaflets including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously.

### **Other information about Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only**

Marketing Authorisations were granted in the UK on 29 April 2008. On 05 September 2012 and 06 September 2012, respectively, the licences for PL 00327/0204 and PL 00327/0206 underwent a change of ownership from Crookes Healthcare Limited to Reckitt Benckiser Healthcare (UK) Limited (PL 00063/0706-0707).

The full PAR for Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only follows this summary.

For more information about treatment with Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only read the package leaflets, or contact your doctor or pharmacist.

This summary was last updated in March 2016.

## TABLE OF CONTENTS

I	Introduction	Page 6
II	Quality aspects	Page 7
III	Non-clinical aspects	Page 9
IV	Clinical aspects	Page 9
V	User consultation	Page 9
VI	Overall conclusion, benefit/risk assessment and recommendation	Page 9
	Table of content of the PAR update	Page 14
	Annex – 1	Page 15

## **I INTRODUCTION**

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Crookes Healthcare Limited Marketing Authorisations for the medicinal products Nurofen Joint & Back Pain Relief 5% Gel (PL 00327/0204) and Nurofen Muscular Pain Relief Gel Pharmacy Only (PL 00327/0206) on 29 April 2008.

The applications were submitted as informed consent applications according to Article 10c of Directive 2001/83/EC, as amended. The applications cross-refer to Ibuprofen 5% Gel (PL 10972/0045) which was first authorised to Goldshield Pharmaceuticals on 24 April 1996.

Nurofen Joint & Back Pain Relief 5% Gel (PL 00063/0706) is a General sales List product (GSL) and Nurofen Muscular Pain Relief Gel Pharmacy Only (PL 00063/0707) is a Pharmacy medicine (P).

The products are indicated as topical analgesics and as anti-inflammatory agents for treatment of backache, rheumatic and muscular pain, sprains, strains and sports injuries.

These products contain the active ingredient ibuprofen. Ibuprofen is a phenylpropionic acid derivative which exerts its anti-inflammatory and analgesic effects directly in inflamed tissues underlying the site of application, mainly by inhibiting prostaglandin biosynthesis.

No new data were submitted nor were necessary to be submitted for these applications, as the data are identical to that of the previously granted cross-reference product.

On 05 September 2012 and 06 September 2012, respectively, the licences for PL 00327/0204 and PL 00327/0206 underwent a change of ownership from Crookes Healthcare Limited to Reckitt Benckiser Healthcare (UK) Limited (PL 00063/0706-0707).

## II QUALITY ASPECTS

### II.1 Introduction

These are informed consent applications for Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only submitted under Article 10c of Directive 2001/83/EC, as amended.

The applications cross-refer to Ibuprofen 5% Gel (PL 10972/0045) which was first authorised to Goldshield Pharmaceuticals on 24 April 1996. The applications are considered valid.

### II.2. Drug Substance

#### Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

### II.3. Medicinal Product

#### Name

The proposed product names are Nurofen Joint & Back Pain Relief 5% Gel and Nurofen Muscular Pain Relief Gel Pharmacy Only. The products have been named in line with current requirements.

#### Strength, pharmaceutical form, route of administration, container and pack sizes

Each 1 gram of gel contains 50 mg of ibuprofen.

The finished product is packed in an aluminium tube with internal epoxy phenolic coating and polyethylene screw cap containing 15, 30, 35 or 50 g (PL 00063/0706) or 100 g (PL 00063/0707) of gel.

Not all pack sizes may be marketed.

The proposed shelf life of the unopened product is 3 years with the storage conditions 'Do not store above 25°C'.

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the cross-reference product.

#### Legal status

On approval, Nurofen Joint & Back Pain Relief 5% Gel (PL 00063/0706) will be available as a General Sales List medicine (GSL) and Nurofen Muscular Pain Relief Gel Pharmacy Only (PL 00063/0707) will be available as a Pharmacy medicine (P).

#### Marketing Authorisation Holder (MAH)/Contact Persons/Company

Crookes Healthcare Limited, 1 Thane Road West, Nottingham, NG2 3AA.

On 05 September 2012 and 06 September 2012, respectively, the licences for PL 00327/0204 and PL 00327/0206 underwent a change of ownership from Crookes Healthcare Limited to Reckitt Benckiser Healthcare (UK) Limited (PL 00063/0706-0707).

The new MAH is Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 4AQ.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

### **Manufacturers**

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

### **Qualitative and quantitative composition**

The proposed composition is consistent with the details registered for the cross-reference product.

### **Manufacturing process**

The proposed manufacturing processes are consistent with the details registered for the cross-reference product and the maximum batch size is stated.

### **Finished product/shelf-life specification**

The proposed finished product specification is in line with the details registered for the cross-reference product.

### **TSE Compliance**

None of the excipients contain materials of animal or human origin. This is consistent with the cross-reference product.

### **Bioequivalence**

No bioequivalence data are required to support these informed consent applications because the proposed products are manufactured to the same formula utilising the same processes as the cross-reference product.

### **Expert Report**

The applicant cross-refers to the data for Ibuprofen 5% Gel (PL 10972/0045) to which these applications are claimed to be identical. This is acceptable.

### **Product Name and Appearance**

See Section II.3 'Medicinal Product; Name' for details of the proposed product names. The appearance of the products is identical to that of the cross-reference product.

## **II.4 Discussion on chemical, pharmaceutical and biological aspects**

The data submitted with the applications is acceptable. The grant of Marketing Authorisations is recommended.

### **III NON-CLINICAL ASPECTS**

#### **Introduction**

As these are informed consent applications submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

#### **Ecotoxicity/environmental risk assessment (ERA)**

Suitable justification has been provided for not submitting an Environmental Risk Assessment. As the applications are identical versions of an already authorised product, it is not expected that environmental exposure will increase following approval of the Marketing Authorisations for the proposed products.

#### **Discussion on the non-clinical aspects**

The grant of Marketing Authorisations is recommended.

### **IV CLINICAL ASPECTS**

#### **Introduction**

As these are informed consent applications submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

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.

#### **Discussion on the clinical aspects**

The grant of Marketing Authorisations is recommended.

### **V USER CONSULTATION**

The package leaflets have been evaluated in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC, as amended. The results show that the package leaflets meet the criteria for readability, as set out in the guideline on the readability of the label and package leaflet of medicinal products for human use.

### **VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION**

The quality of the products is acceptable, and no new non-clinical or clinical concerns have been identified. The applicant's products are identical to the cross-reference product. Extensive clinical experience with ibuprofen is considered to have demonstrated the therapeutic value of the compound. The benefit/risk balance is, therefore, considered to be positive.



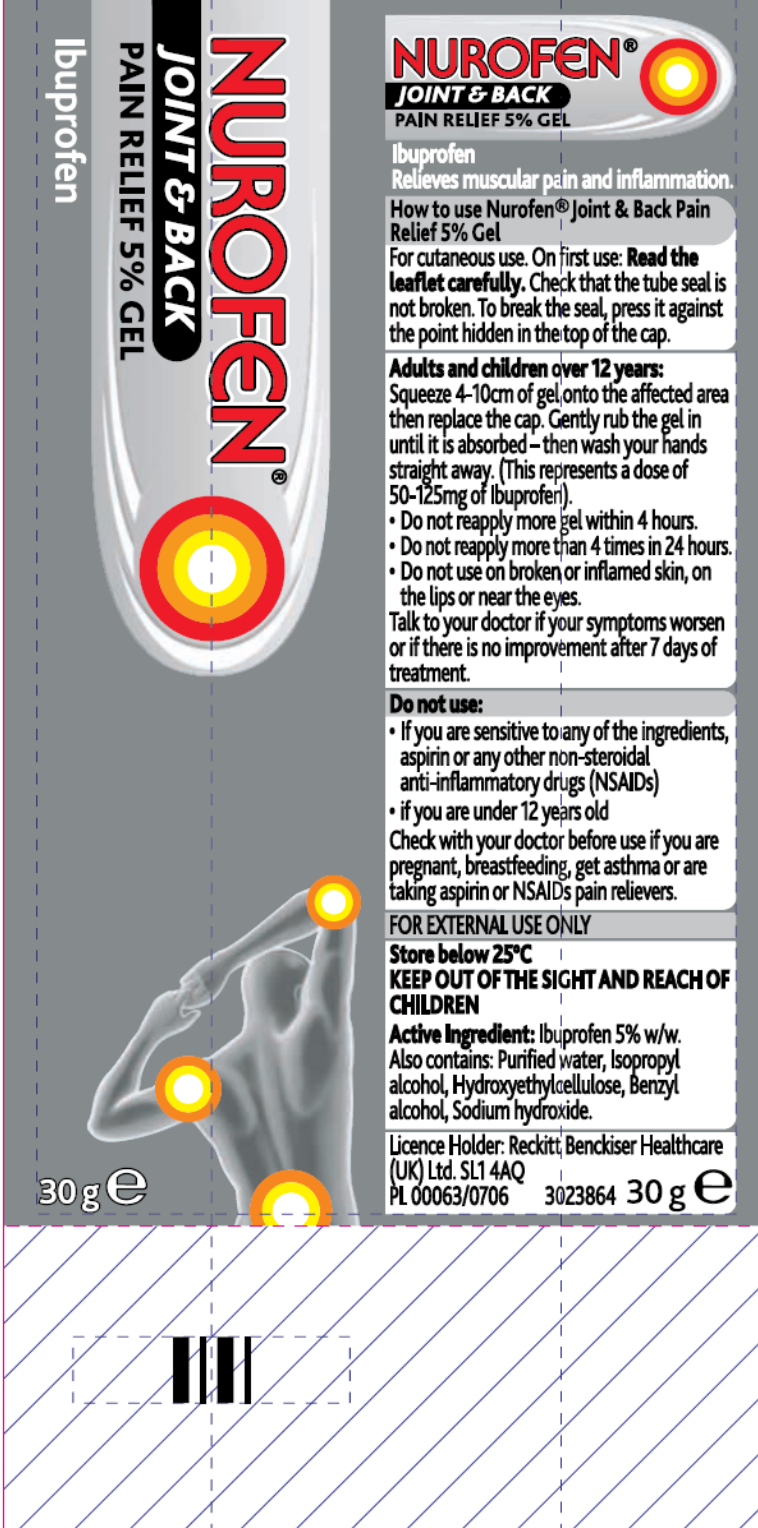
**Summaries of Product Characteristics (SmPC), Patient Information Leaflets (PIL) and Labels**

The Summaries of Product Characteristics and Patient Information Leaflets (PIL) are consistent with the details registered for the cross-reference product.

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The currently approved labelling is presented below:





The image shows the packaging for Nurofen Joint & Back Pain Relief 5% Gel. The packaging is a white tube with a red and yellow target logo. The text on the tube includes 'Ibuprofen', 'NUROFEN®', 'JOINT & BACK', and 'PAIN RELIEF 5% GEL'. Below the tube is a diagram of a human figure with three target logos on the shoulder, elbow, and wrist, indicating areas of application. The bottom left of the packaging shows '30g e' and a barcode.

**NUROFEN®**  
**JOINT & BACK**  
PAIN RELIEF 5% GEL

Ibuprofen

**NUROFEN®**  
**JOINT & BACK**  
PAIN RELIEF 5% GEL

30g e

**NUROFEN®**  
**JOINT & BACK**  
PAIN RELIEF 5% GEL

**Ibuprofen**  
Relieves muscular pain and inflammation.

**How to use Nurofen® Joint & Back Pain Relief 5% Gel**  
For cutaneous use. On first use: **Read the leaflet carefully.** Check that the tube seal is not broken. To break the seal, press it against the point hidden in the top of the cap.

**Adults and children over 12 years:**  
Squeeze 4-10cm of gel onto the affected area then replace the cap. Gently rub the gel in until it is absorbed – then wash your hands straight away. (This represents a dose of 50-125mg of Ibuprofen).

- Do not reapply more gel within 4 hours.
- Do not reapply more than 4 times in 24 hours.
- Do not use on broken or inflamed skin, on the lips or near the eyes.

Talk to your doctor if your symptoms worsen or if there is no improvement after 7 days of treatment.

**Do not use:**

- If you are sensitive to any of the ingredients, aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs)
- if you are under 12 years old

Check with your doctor before use if you are pregnant, breastfeeding, get asthma or are taking aspirin or NSAIDs pain relievers.

**FOR EXTERNAL USE ONLY**

**Store below 25°C**  
**KEEP OUT OF THE SIGHT AND REACH OF CHILDREN**

**Active Ingredient:** Ibuprofen 5% w/w.  
Also contains: Purified water, Isopropyl alcohol, Hydroxyethylcellulose, Benzyl alcohol, Sodium hydroxide.

Licence Holder: Reckitt, Benckiser Healthcare (UK) Ltd. SL1 4AQ  
PL 00063/0706 3023864 30 g e



**NUROFEN**  
**Muscular Pain Relief Gel**  
**Pharmacy Only**

Relieves muscular pain and inflammation.

**How to use Nurofen Muscular Pain Relief Gel Pharmacy Only**  
For cutaneous use. On first use: **Read the leaflet carefully.** Check that the tube seal is not broken. To break the seal, press it against the point hidden in the top of the cap.

**Adults and children over 14 years:** Squeeze 4–10 cm of gel onto the affected area then replace the cap. Gently rub the gel in until it is absorbed – then wash your hands straight away. (This represents a dose of 50–125 mg of Ibuprofen.)

- Do not reapply more gel within 4 hours.
- Do not apply more than 4 times in 24 hours.
- Do not use on broken or inflamed skin, on the lips or near the eyes.
- Talk to your doctor if your symptoms worsen or if there is no improvement after two weeks treatment.

**Do not use:**

- **If you are sensitive to any of the ingredients, aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs).**
- **If you are under 14 years old.**

Check with your doctor before use if you are pregnant, get asthma or are taking aspirin or NSAIDs pain relievers.

FOR EXTERNAL USE ONLY

Store below 25°C

**KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN**

**Active ingredient:** ibuprofen 5% w/w. Also contains: Purified water, Isopropyl alcohol, Hydroxyethylcellulose, Benzyl alcohol, Sodium hydroxide.

Licence holder: Reckitt Benckiser Healthcare (UK) Ltd. SL1 4AQ.



PL 00063/0707 **P**

100 g e

**NUROFEN**  
Ibuprofen 5%  
**Muscular Pain Relief Gel**  
Pharmacy Only

TARGETED RELIEF FOR PAIN

for muscular pain



XXXXX

### Table of content of the PAR update

Steps taken after the initial procedure with an influence on the Public Assessment Report

<b>Scope</b>	<b>Procedure number</b>	<b>Product Information affected</b>	<b>Date of start of the procedure</b>	<b>Date of end of procedure</b>	<b>Approval/ non approval</b>	<b>Assessment report attached</b>
Type II variation to update section 5.2 of the SmPC following the Company Core Data sheet	PL 00063/0707 - 0012	SmPC	17/03/15	29/01/16	Approved	Y (annex 1)

## Annex 1

**Reference:** PL 00063/0707 – 0012

**Product:** Nurofen Muscular Pain Relief Gel Pharmacy Only

**Marketing Authorisation Holder:** Reckitt Benckiser Healthcare (UK) Limited

**Active Ingredient(s):** Ibuprofen

**Reason:**

To update section 5.2 (Pharmacokinetic properties) of the SmPC following the Company Core Data Sheet.

**Supporting Evidence**

A revised SmPC fragment 5.2 has been provided, along with the Clinical Overview and application form. The currently approved PIL and labelling is acceptable and needs no further revisions.

**Evaluation**

The amended section of the SmPC is satisfactory.

The current approved UK version of the Summary of Product Characteristics (SmPC) is available on the MHRA website.

**Decision**

Approved on 29 January 2016