Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

UKPAR

Ibuprofen 10% w/w gel
Nurofen Joint & Back Pain Relief Max Strength 10 % Gel
Boots Max Strength Ibuprofen 10% Gel (Ibuprofen)

PL 10972/0089

Mercury Pharma Group Ltd

LAY SUMMARY
Ibuprofen 10% w/w gel
Nurofen Joint & Back Pain Relief Max Strength 10 % Gel
Boots Max Strength Ibuprofen 10% Gel
PL 10972/0089

This is a summary of the Public Assessment Report (PAR) for Ibuprofen 10% w/w gel, Nurofen Joint & Back Pain Relief Max Strength 10% Gel, Boots Max Strength Ibuprofen 10% Gel (PL 10972/0089). This medicinal product will be referred to as Ibuprofen 10% w/w Gel in the remainder of this report, for ease of reading.

This summary explains how Ibuprofen 10% w/w Gel was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use Ibuprofen 10% w/w Gel.

For practical information about using Ibuprofen 10% w/w Gel, patients should read the package leaflets or contact their doctor or pharmacist.

What is Ibuprofen 10% w/w Gel and what is it used for?
Ibuprofen 10% w/w Gel is the same as Fenbid Forte 10% Gel (PL 10972/0082), approved on 5 January 1999, authorised to the same Marketing Authorisation Holder (Mercury Pharma Group Ltd).

Ibuprofen 10% w/w Gel is a General Sales List (GSL) product, used to treat a number of painful conditions affecting the joints and muscles such as backache, rheumatic pain, muscular aches, pains or swellings such as sprains, strains and other sports injuries.

How does Ibuprofen 10% w/w Gel work?
Ibuprofen 10% w/w Gel contains the active substance ibuprofen, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This medicine reduces pain and inflammation, and brings down high temperature.

How is Ibuprofen 10% w/w Gel used?
Ibuprofen 10% w/w Gel is for topical (on the skin) application only. This medicine is for external use only and should not be taken by mouth.

In adults, the elderly and children over 12 years, the recommended dose is 2-5 cm of 10 %w/w gel squeezed from the tube and massaged onto the affected area until absorbed. This dose should not be repeated more frequently than every four hours and it should not be applied more than four times a day in any 24 hour period. The amount of gel squeezed would be equivalent to 50 to 125 mg of gel.

Ibuprofen 10% w/w Gel is not recommended for use in children under 12 years of age.

For further information on how Fenbid/Phorpain gel is used, please refer to the Summaries of Product Characteristics and the Patient Information Leaflets available on the MHRA website.

What benefits of Ibuprofen 10% w/w Gel have been shown in studies?
As Ibuprofen 10% w/w Gel is considered to be identical to the reference product, Fenbid Forte 10% Gel (PL 10972/0082), the benefits and risks are taken as being the same as those for the reference product.

What are the possible side effects from Ibuprofen 10% w/w Gel?
Like all medicines, Ibuprofen 10% w/w Gel can cause side effects, although not everybody gets them.

For the full list of all side effects reported with Ibuprofen 10% w/w Gel, see Section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Ibuprofen 10% w/w Gel approved?
No new or unexpected safety concerns arose from this application. It was, therefore, considered that the benefits of Ibuprofen 10% w/w Gel outweigh the risks, and the grant of a Marketing Authorisation was recommended.

What measures are being taken to ensure the safe and effective use of Ibuprofen 10% w/w Gel?
A Risk Management Plan (RMP) has been developed to ensure that Ibuprofen 10% w/w Gel is used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics and the package leaflets for Fenbid/Phorpain gel, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Ibuprofen 10% w/w Gel
A Marketing Authorisation was granted in the UK on 27 July 2012.

For more information about taking Ibuprofen 10% w/w Gel, read the package leaflet, or contact your doctor or pharmacist.

The full PAR for Ibuprofen 10% w/w Gel follows this summary.

This summary was last updated in May 2016.

Ibuprofen 10% w/w gel
Nurofen Joint & Back Pain Relief Max Strength 10 % Gel
Boots Max Strength Ibuprofen 10% Gel
PL 10972/0089

TABLE OF CONTENTS

I INTRODUCTION

The Medicines and Healthcare Products Regulatory Agency (MHRA) granted a marketing authorisation (licence) for the medicinal product Ibuprofen 10% w/w gel, Nurofen Maximum Strength 10 % Gel (PL 10972/0089) to Goldshield Group Limited on the 27 July 2012. This medicine was used for the relief of pain and inflammation associated with backache, rheumatic and muscular pain, strains, sprains, neuralgia, sports injuries and for the relief of pain of non-serious arthritic conditions.

This application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC as amended, cross-referring to Fenbid Forte 10% gel (PL 10972/0082), which was granted a marketing authorisation on 5th January 1999.

No new data were submitted nor were they necessary for this simple application, as the data are identical to those of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) was generated.

A pharmacovigilance system has been provided with this application and is satisfactory. A suitable justification for non-submission of the Risk Management Plan has been provided.

No environmental risk assessment (ERA) has been undertaken, as this is not considered necessary. This product is essentially similar and the therapeutic indications and posology of the finished product are the same as those already licensed products. The applicant's justification for absence of an ERA is satisfactory.

A variation to change the name of the marketing authorisation holder from Goldshield Group Limited to Mercury Pharma Group Limited was approved on 10 December 2012.

A variation to change the legal classification from pharmacy (P) to general sales list (GSL) and to amend the pack sizes was approved on 6 February 2013. This variation also resulted in a change to the indication including removal of use in the relief of pain caused by non-serious arthritic conditions and nerve pain (neuralgia).

A variation to change the packaging of the tube cap from polyethylene to polypropylene was granted on 6 September 2013.

An additional product name of "Boots Max Strength Ibuprofen 10% Gel" was added on 11 November 2013.

The name of the product "Nurofen Maximum Strength 10% Gel" was amended to "Nurofen Joint & Back Pain Relief Max Strength 10% Gel" on 23 October 2015.

II Quality aspects

II.1 Introduction

This is an informed consent application for Ibuprofen 10% w/w gel, Nurofen Maximum Strength 10 % Gel, submitted under Article 10c of Directive 2001/83/EC as amended. This product is cross-referring to Fenbid Forte 10% gel (PL 10972/0082), approved on 5th January 1999 to the marketing authorisation holder, Goldshield Group Limited. The current application is considered valid.

II.2. Drug Substance

Drug substance specification

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

II.3 Medicinal Product

Name(s)

The proposed names of the product are Ibuprofen 10% w/w gel, Nurofen Maximum Strength 10 % Gel. The product has been named in line with current requirements.

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

The product is a gel for topical use and contains the active ingredient ibuprofen.

The product is packed in collapsible aluminium tubes with internal protective lacquer with HDPE screw caps. Pack sizes of 30g and 50g.

The packaging and pack sizes are the same as those for the reference product.

The proposed shelf life is 36 months with a storage conditions “Do not store above 25ºC” and “Keep the tube in the outer carton in order to protect from light”. The shelf-life and storage conditions are identical to those for the reference product and are satisfactory.

Legal status

This product is supplied through a Pharmacy (P).

Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Goldshield Group Limited, (trading as Goldshield Pharmaceuticals), NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey CR0 0XT, UK

Manufacturers

The proposed manufacturing sites are consistent with those registered for the 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 reference product.

Manufacturing process
The proposed manufacturing process is consistent with the details registered for the reference product and the maximum full scale batch size is stated.

Finished product/shelf-life specifications
The proposed finished product and shelf-life specification are in line with the details registered for the reference product.

Drug substance specificatio
The proposed drug substance specification conforms to the current European Pharmacopoeia monograph for ibuprofen and is in line with those for the reference product.

TSE Compliance
No materials of human or animal origin have been used in the manufacture of this product. This is consistent with the reference product.

Bioequivalence
No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula utilising the same process as the reference product Fenbid Forte 10% gel (PL 10972/0082).

Expert Report
The applicant has included detailed expert reports of the application. Signed declarations and copies of the experts' CVs are enclosed for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

II.4 Discussion on chemical, pharmaceutical and biological aspects

The quality data for this application are consistent with those approved for Fenbid Forte 10% gel (PL 10972/0082) and, as such, have been judged to be satisfactory. The grant of a Marketing Authorisation is recommended.

III Non-clinical aspects

As this is an abridged simple application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

A suitable justification has been provided for not submitting an environmental risk assessment.

The grant of a Marketing Authorisation is recommended.

IV Clinical aspects

As this is an abridged simple application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate

evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

V User consultation

User-testing of the patient information leaflet (PIL) has been accepted based on the bridging report provided by the applicant making reference to the successful user-testing of the PIL for Fenbid Forte 10% Gel (PL 10972/0082).

VI Overall conclusion, benefit/risk assessment and recommendation

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

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

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

The updated labelling is provided in Annex 1.

Table of content of the PAR update

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

Date submitted	Application type	Scope	Outcome
30/11/2015	II	To update Section 4.2 and 4.4 of the SmPC, PIL and labelling to reflect the change of age limit in children from 14 to 12 years. The current approved SmPC already reflects age limit in children as 12 years for PL 10972/0045, PL 10972/0089 and PL 10972/0091.	Granted 18/03/2016

Annex 1

Reference: PL 10972/0089-0020
Product: Boots Max Strength Ibuprofen 10% Gel, Ibuprofen 10% w/w gel, Nurofen Joint & Back Pain Relief Max Strength 10 % Gel
Marketing Authorisation Holder: Mercury Pharma Group Limited
Active Ingredient(s): Ibuprofen

Reason: To update Section 4.2 and 4.4 of the SmPC, PIL and labelling to reflect the change of age limit in children from 14 to 12 years.

The current approved SmPC already reflects age limit in children as 12 years for PL 10972/0045, PL 10972/0089 and PL10972/0091.

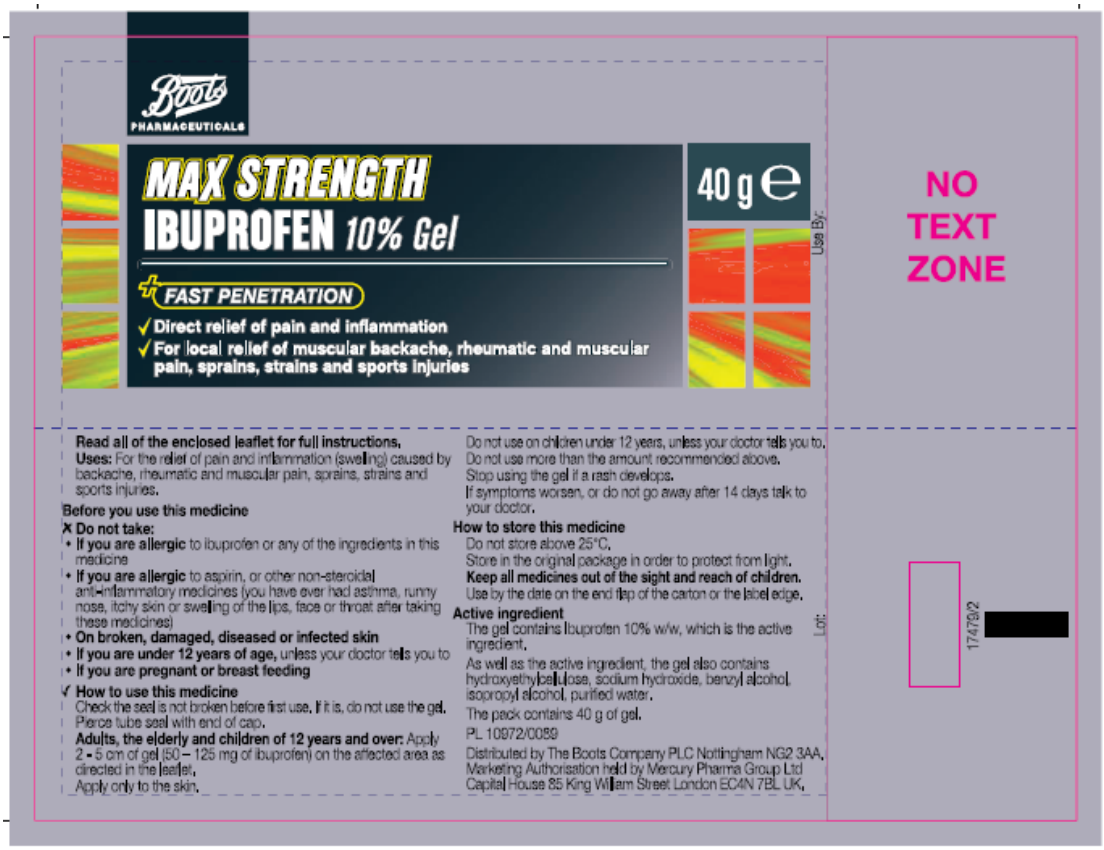
Supporting Evidence
Updated versions of the SmPC, PIL and labelling have been submitted

Evaluation
The changes are accepted and are in line with the current approved changes in PL 10972/0045, PL 10972/0089 and PL 10972/0091.

Conclusion
The change is acceptable. The current SmPCs and PIL are available on the MHRA website. The updated labelling is presented below.

Decision - Approved 18/03/2016


Read all of the enclosed leaflet for full instructions.
Uses: For the relief of pain and inflammation (swelling) caused by backache, rheumatic and muscular pain, sprains, strains and sports injuries.
Before you use this medicine
Do not use:
If you are allergic to ibuprofen or any of the ingredients in this medicine
If you are allergic to aspirin, or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
On broken, damaged, diseased or infected skin
If you are under 12 years of age, unless your doctor tells you to
If you are pregnant or breastfeeding
How to use this medicine
Check the seal is not broken before first use. If it is, do not use the gel.
Pierce tube seal with end of cap.
Age | How much to use | How often to use
Adults and children of 12 years and over | 2 - 5 cm of gel (50 – 125 mg of ibuprofen) on the affected area | Every 4 hours, if you need to. Don't use more than 4 times in 24 hours
Don't use more than every 4 hours.
Apply only to the skin.
Gently massage the gel into the affected area until it is absorbed.
Wash your hands as soon as you have used the gel.
Avoid contact with the eyes, mouth, lips or nose, or inflamed or broken skin.
Do not apply plasters or dressings over the gel.
Do not use on children under 12 years, unless your doctor tells you to.
Do not use more than the amount recommended above.
Stop using the gel if a rash develops.
If symptoms worsen, or do not go away after 14 days talk to your doctor.
How to store this medicine
Do not store above 25°C.
Store in the original package in order to protect from light.
Keep all medicines out of the sight and reach of children.
Use by the date on the end flap of the carton.
If you need more advice ask your pharmacist.
Boots PHARMACEUTICALS
MAX STRENGTH IBUPROFEN 10% Gel
FAST PENETRATION
Direct relief of pain and inflammation
For local relief of muscular backache, rheumatic and muscular pain, sprains, strains and sports injuries
40 g e
Lot:
Use By:
Active ingredient
The gel contains Ibuprofen 10% w/w, which is the active ingredient.
As well as the active ingredient, the gel also contains hydroxyethylcellulose, sodium hydroxide, benzyl alcohol, isopropyl alcohol, purified water.
The pack contains 40 g of gel.
PL 10972/0089
Distributed By: The Boots Company PLC Nottingham NG2 3AA, Marketing Authorisation held by Mercury Pharma Group Ltd Capital House 85 King William Street London EC4N 7BL UK.
5 045091 547947
15-47-841
174802


Boots PHARMACEUTICALS
MAX STRENGTH IBUPROFEN 10% Gel
FAST PENETRATION
Direct relief of pain and inflammation
For local relief of muscular backache, rheumatic and muscular pain, sprains, strains and sports injuries
40 g e
Use By:
NO TEXT ZONE
Read all of the enclosed leaflet for full instructions.
Uses: For the relief of pain and inflammation (swelling) caused by backache, rheumatic and muscular pain, sprains, strains and sports injuries.
Before you use this medicine
Do not take:
If you are allergic to ibuprofen or any of the ingredients in this medicine
If you are allergic to aspirin, or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
On broken, damaged, diseased or infected skin
If you are under 12 years of age, unless your doctor tells you to
If you are pregnant or breast feeding
How to use this medicine
Check the seal is not broken before first use. If it is, do not use the gel.
Pierce tube seal with end of cap.
Adults, the elderly and children of 12 years and over: Apply 2 - 5 cm of gel (50 – 125 mg of ibuprofen) on the affected area as directed in the leaflet.
Apply only to the skin.
Do not use on children under 12 years, unless your doctor tells you to.
Do not use more than the amount recommended above.
Stop using the gel if a rash develops.
If symptoms worsen, or do not go away after 14 days talk to your doctor.
How to store this medicine
Do not store above 25°C.
Store in the original package in order to protect from light.
Keep all medicines out of the sight and reach of children.
Use by the date on the end flap of the carton or the label edge.
Active ingredient
The gel contains Ibuprofen 10% w/w, which is the active ingredient.
As well as the active ingredient, the gel also contains hydroxyethylcellulose, sodium hydroxide, benzyl alcohol, isopropyl alcohol, purified water.
The pack contains 40 g of gel.
PL 10972/0089
Distributed by The Boots Company PLC Nottingham NG2 3AA, Marketing Authorisation held by Mercury Pharma Group Ltd Capital House 85 King William Street London EC4N 7BL UK.
Lot:
174802


NUROFEN
JOINT & BACK PAIN RELIEF
MAX STRENGTH 10% GEL
Ibuprofen
40 g
Last Bar
First Bar
FPO
RB187350
TO RELIEVE PAIN AND INFLAMMATION IN:
• Backache
• Muscular and rheumatic pain
• Strains and sprains
• Sport injuries
Read carefully enclosed leaflet before use.
DO NOT USE IF YOU:
• are allergic to any of the ingredients, aspirin or any other pain relievers known as NSAIDs (non-steroidal anti-inflammatory drugs).
• are under 12 years, pregnant or breastfeeding, except on the advice of a doctor.
DO NOT APPLY MORE OF THIS MEDICINE THAN THE LABEL TELLS YOU TO.
Consult your doctor before use if you are asthmatic, have active peptic ulcer, kidney problems or are taking aspirin or other pain killers.
Talk to your doctor if your symptoms worsen or if there is no improvement after 14 days.
HOW TO USE:
Check the tube seal is not broken before first use. Invert cap and press to break seal.
Adults, the elderly and children over 12 years: Squeeze 2 to 5cm (i.e. 0.8 to 2 inches) of gel from the tube and rub into the affected area until absorbed, then wash your hands straight away. The amount of gel squeezed would be equivalent to 50 to 125mg of Ibuprofen.
Do not cover with plaster or dressing. Do not apply more than 4 times in 24hrs. Do not reapply within 4 hours. Do not use it on broken or damaged skin, on the lips, near the eyes, mouth or nose. Avoid excessive exposure of the treated area to sunlight. Discontinue if a rash develops.
USE THIS MEDICINE ONLY ON YOUR SKIN.
Please, do not move or erase our material code
Batch No:
Use before:
0 000000 000000
Active Ingredient:
Ibuprofen 10% w/w. Also contains: purified water, isopropyl alcohol, hydroxyethylcellulose, benzyl alcohol, sodium hydroxide.
Do not store above 25°C. Keep the tube in the carton in order to protect from light.
Keep out of the sight and reach of children.
PL 10972/0089
MA Holder:
Mercury Pharma Group Ltd., Capital House, 85 King William Street, London EC4N 7BL, UK.
Distributed by:
Reckitt Benckiser Healthcare (UK) Ltd, HU8 7DS.

NUROFEN®
JOINT & BACK PAIN RELIEF
MAX STRENGTH 10% GEL
Ibuprofen

Relieves muscular pain and inflammation

How to use this Gel

Read the leaflet carefully. Before first use, check that the seal is not broken then pierce it with the point in the end of the cap to break the seal.

Adults, the elderly and children over 12 years: Squeeze 2 to 5 cm (i.e. 0.8 to 2 inches) of gel from the tube and rub into the affected area until absorbed-then wash your hands straight away. The amount of gel squeezed would be equivalent to 50 to 125mg of Ibuprofen.

- Do not apply plasters or dressings over the gel.
- Do not reapply more gel within 4 hours.
- Do not apply more than 4 times in 24 hours.
- Do not use on broken or damaged skin, on the lips or near the eyes.
- Discontinue use if a skin rash develops.
- Avoid excessive exposure to sunlight of area treated.
- Talk to your doctor if your symptoms worsen or if there is no improvement after 14 days.

DO NOT USE:

- **If you are allergic to any of the ingredients, aspirin or any other NSAIDs (non-steroidal anti-inflammatory drugs).**
- **If you are under 12 years, pregnant or breastfeeding, except on the advice of a doctor.**

Consult your doctor before use if you are asthmatic, have active peptic ulcer, kidney problems or are taking aspirin or other pain killers.

DO NOT APPLY MORE OF THIS MEDICINE THAN THE LABEL TELLS YOU TO.

USE THIS MEDICINE ONLY ON YOUR SKIN.

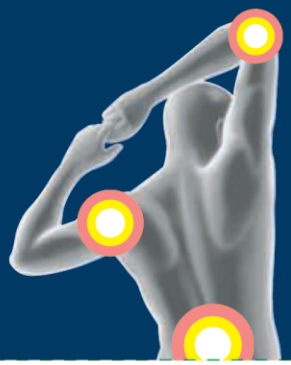
Do not store above 25°C. Keep the tube in the carton in order to protect from light. Keep out of the sight and reach of children.

Active Ingredient: ibuprofen 10% w/w. Also contains: purified water, isopropyl alcohol, hydroxyethylcellulose, benzyl alcohol, sodium hydroxide.

MA Holder: Mercury Pharma Group Ltd., Capital House, 85 King William Street, London EC4N 7BL, UK.
Distributed by: Reckitt Benckiser Healthcare (UK) Ltd, HU8 7DS PL 10972/0089 40 g e

RB187356 TEXT FREE AREA

Ibuprofen
NUROFEN®
JOINT & BACK PAIN RELIEF
MAX STRENGTH 10% GEL



40 g e

FPO
RB187356

CODING AREA ONLY
(NO TEXT OR GRAPHICS
WHITE BACKGROUND)

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON for Aluminium tube containing 30g gel

1. NAME OF THE MEDICINAL PRODUCT

Ibuprofen 10% w/w gel

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Ibuprofen 10% w/w.

3. LIST OF EXCIPIENTS

Also contains purified water, isopropyl alcohol, hydroxyethylcellulose, benzyl alcohol, sodium hydroxide

4. PHARMACEUTICAL FORM AND CONTENTS

Gel for topical application

30g
40g

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Topical application.
Read carefully enclosed leaflet before use.

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

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not use:
• If you are allergic to any of the ingredients, asprin or any other pain relievers known as NSAIDs (Non steroidal anti-inflammatory drugs).
•Are under 12 years, pregnant or breastfeeding, except on the advice of a doctor.

Do not apply more of this medicine than the label tells you to.
Consult your doctor before use if you are asthamatic, have active peptic ulcer, kidney problem or are taking aspirin or other pain killers.
Talk to your doctor if your symptoms worsen or if there is no improvement after 14 days.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the tube in the outer carton in order to protect from light..

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

No special instructions.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mercury Pharma Group Ltd,
Capital House,
85 King William Street,
London EC4N 7BL, UK

12. MARKETING AUTHORISATION NUMBER(S)

PL 10972/0089

13. BATCH NUMBER

LOT:

14. GENERAL CLASSIFICATION FOR SUPPLY

GSL

15. INSTRUCTIONS ON USE

To relieve pain and inflammation in:

- Backache
- Muscular or rheumatic pain
- Strains and sprains
- Sport injuries

Read carefully enclosed leaflet before use.

Check the tube seal is not broken before first use. Invert cap and press to break seal.
Directions: Adults, the elderly and children over 12 years
Squeeze 2 to 5cm (i.e., 0.8 to 2 inches) of gel from the tube and rub into the affected area until absorbed- then wash you hands straight away. The amount of gel squeezed would be equivalent to 50 to 125 mg of Ibuprofen.

Replace the cap. Gently rub the gel until it is absorbed.Wash your hands after use.
Do not cover with plaster or dressing.Do not apply more than 4 times in 24 hours. Do not apply within 4 hours.
Do not use it on broken or damaged skin, on the lips, near the eyes, mouth or nose.
Avoid excessive exposure of the treated area to sunlight. Discontinue if rash develops.

Use this medicine only on your skin.

16. INFORMATION IN BRAILLE

Ibuprofen 10% gel

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON for Aluminium tube containing 40g gel

1. NAME OF THE MEDICINAL PRODUCT

Ibuprofen 10% w/w gel

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Ibuprofen 10% w/w.

3. LIST OF EXCIPIENTS

Also contains purified water, isopropyl alcohol, hydroxyethylcellulose, benzyl alcohol, sodium hydroxide .

4. PHARMACEUTICAL FORM AND CONTENTS

Gel for topical application

30g
40g

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Topical application.

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

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not use:
• If you are allergic to any of the ingredients, asprin or any other pain relievers known as NSAIDs (Non steroidal anti-inflammatory drugs).
•Are under 12 years, pregnant or breastfeeding, except on the advice of a doctor.

Do not apply more of this medicine than the label tells you to.
Consult your doctor before use if you are asthamatic, have active peptic ulcer, kidney problem or are taking aspirin or other pain killers.
Talk to your doctor if your symptoms worsen or if there is no improvement after 14 days.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the tube in the outer carton in order to protect from light..

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

No special instructions.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mercury Pharma Group Ltd,
Capital House,
85 King William Street,
London EC4N 7BL, UK

12. MARKETING AUTHORISATION NUMBER(S)

PL 10972/0089

13. BATCH NUMBER

LOT:

14. GENERAL CLASSIFICATION FOR SUPPLY

GSL

15. INSTRUCTIONS ON USE

To relieve pain and inflammation in:

- Backache
- Muscular or rheumatic pain
- Strains and sprains
- Sport injuries

Read carefully enclosed leaflet before use.

Check the tube seal is not broken before first use. Invert cap and press to break seal.
Directions: Adults, the elderly and children over 12 years
Squeeze 2 to 5cm of the gel (equivalent to 50-125mg of ibuprofen onto the affected skin area.

Replace the cap. Gently rub the gel until it is absorbed.Wash your hands after use.
Do not cover with plaster or dressing.Do not apply more than 4 times in 24 hours. Do not apply within 4 hours.
Do not use it on broken or damaged skin, on the lips, near the eyes, mouth or nose.
Avoid excessive exposure of the treated area to sunlight. Discontinue if rash develops.

Use this medicine only on your skin.

16. INFORMATION IN BRAILLE

Ibuprofen 10% gel