Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

# Public Assessment Report

# National Procedure

# NUROFEN MAXIMUM STRENGTH MIGRAINE PAIN 684MG CAPLETS
# NUROFEN EXPRESS 684MG CAPLETS
# (Ibuprofen lysine)

## UK Licence Number: PL 00063/0384

## Reckitt Benckiser Healthcare (UK) Limited

Medicines and Healthcare Products Regulatory Agency

# LAY SUMMARY

Nurofen Maximum Strength Migraine Pain 684mg Caplets
Nurofen Express 684mg Caplets
(Ibuprofen lysine)

This is a summary of the Public Assessment Report (PAR) for Nurofen Maximum Strength Migraine Pain 684mg Caplets/Nurofen Express 684mg Caplets (PL 00063/0384). It explains how Nurofen Maximum Strength Migraine Pain 684mg Caplets/Nurofen Express 684mg Caplets 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 Maximum Strength Migraine Pain 684mg Caplets/Nurofen Express 684mg Caplets.

For practical information about using Nurofen Maximum Strength Migraine Pain 684mg Caplets/Nurofen Express 684mg Caplets, patients should read the package leaflet or contact their doctor or pharmacist.

This medicinal product will be referred to as Nurofen Caplets for the remainder of this summary, for ease of reading.

**What are Nurofen Caplets and what are they used for?**
Nurofen Caplets are used for the relief of headache and migraine pain.

**How do Nurofen Caplets work?**
This medicine contains the active substance ibuprofen lysine, which belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling, and high temperature.

**How are Nurofen Caplets used?**
This medicine is available in a pharmacy, without a prescription.

This medicine is for short term use only. Patients should take the lowest dose for the shortest time necessary to relieve symptoms.

Adults, the elderly and adolescents between 12 and 18 years, should take one caplet with water, up to three times a day, as required. They should not take more than 3 caplets in 24 hours.

This product should not be given to children under 12 years of age.
In children and adolescents between 12 and 18 years, if this product is required for more than 3 days, or if symptoms worsen, a doctor should be consulted.

Adults should not take this medicine for longer than 10 days, unless a doctor tells them to. If symptoms persist or the pain worsens, or if any new symptoms occur, patients should consult their doctor or pharmacist.

**What benefits of Nurofen Caplets have been shown in studies?**
A lower strength of the product has already been approved for use - Nurofen Migraine Pain (PL 00327/0125) and the active ingredient ibuprofen has been used in medicinal products for a long time. Studies were conducted to show that this product is bioequivalent to an equivalent dose of Nurofen Migraine Pain (PL 00327/0125). Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

## What are the possible side effects of Nurofen Caplets?

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

For the full list of all side effects reported with Nurofen Caplets, see section 4 of the package leaflet available on the MHRA website.

## Why were Nurofen Caplets approved?

The MHRA decided that this medicine's benefits are greater than its risks and recommended that it be approved for use.

## What measures are being taken to ensure the safe and effective use of Nurofen Caplets?

Safety information has been included in the Summary of Product Characteristics (SmPC) and the package leaflet for Nurofen Caplets, 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 Caplets

A Marketing Authorisation was granted in the UK to Crookes Healthcare Limited (PL 00327/0143) on 17 January 2006.

The licence subsequently underwent a Change of Ownership to Reckitt Benckiser Healthcare (UK) Limited (PL 00063/0384) on 19 April 2011.

The full PAR for Nurofen Caplets follows this summary. For more information about treatment with Nurofen Caplets read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in November 2017.

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# I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA considered that the application for Nurofen Maximum Strength Migraine Pain 684mg Caplets/Nurofen Express 684mg Caplets could be approved. The application was submitted via the National Procedure.

This product is not subject to medical prescription, but will be supplied through pharmacies only (legal status P).

The application was submitted under Article 8(3) of Directive 2001/83/EC, as amended, as a line extension of the authorised medicinal product Nurofen Migraine Pain tablets (PL 00327/0125; containing 342mg ibuprofen lysine) which was granted a Marketing Authorisation on 27 July 2000. The authorised formulation is half the strength of the proposed product and in direct proportion. The application relies upon the use of data filed to date, for PL 00327/0125, supplemented by data to meet the extent to which the products are not the same. PL 00327/0125 subsequently underwent a change of ownership to Reckitt Benckiser Healthcare (UK) Limited (PL 00063/0380) on 19 April 2009.

Nurofen Maximum Strength Migraine Pain 684mg Caplets/Nurofen Express 684mg Caplets are indicated for the relief of headache and migraine.

This product contains the active substance ibuprofen lysine, which is the lysine salt of ibuprofen. Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. In humans, ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

Clinical evidence demonstrates that when 1-caplet dose of 684 mg ibuprofen lysine (equivalent to 400 mg ibuprofen) is taken, the pain-relieving effects can last for up to 8 hours.

No new non-clinical studies were conducted, which is acceptable given that the application is for a new product containing a known active substance.

The applicant has submitted the results of pharmacokinetic studies conducted with the previously approved product Nurofen Migraine Pain tablets, containing 342mg ibuprofen lysine (PL 00327/0125) The clinical studies were conducted according to Good Clinical Practice (GCP) principles.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product type at all sites responsible for the manufacture and assembly of this product.

A Marketing Authorisation was granted in the UK to Crookes Healthcare Limited (PL 00327/0143) on 17 January 2006.

The licence subsequently underwent a Change of Ownership to Reckitt Benckiser Healthcare (UK) Limited (PL 00063/0384) on 19 April 2011.

# II QUALITY ASPECTS

## II.1 Introduction

Nurofen Maximum Strength Migraine Pain 684mg Caplets/Nurofen Express 684mg Caplets are white, film-coated, capsule-shaped tablets, printed with an identifying logo in black on one face. Each caplet contains 684mg ibuprofen lysine (equivalent to 400mg ibuprofen).

Other ingredients consist of the pharmaceutical excipients, namely povidone, sodium starch glycolate, magnesium stearate, hypromellose, talc, Opaspray White M-1-7111B (contains hypromellose and titanium dioxide (E171)) and black printing ink (contains shellac, iron oxide black (E172) and propylene glycol).

The finished product is packaged as follows in:

- A blister pack consisting of opaque, white 250µm polyvinyl chloride/40gsm polyvinylidene chloride laminate heat sealed to 20µm aluminium foil. The blisters are packed in cardboard cartons, containing 4, 6, 8, 10, 12, 16 and 24 tablets.
- A blister pack consisting of opaque, white 250µm polyvinyl chloride/90gm² polyvinylidene chloride laminate heat sealed to 20µm aluminium foil. The blisters are packed in cardboard cartons, containing 4, 6, 8, 10, 12, 16 and 24 tablets.
- A blister pack consisting of opaque, white 250µm polyvinyl chloride/120gm² polyvinylidene chloride laminate heat sealed to 20µm aluminium foil. The blisters are packed in cardboard cartons, containing 4, 6, 8, 10, 12, 16 and 24 tablets.

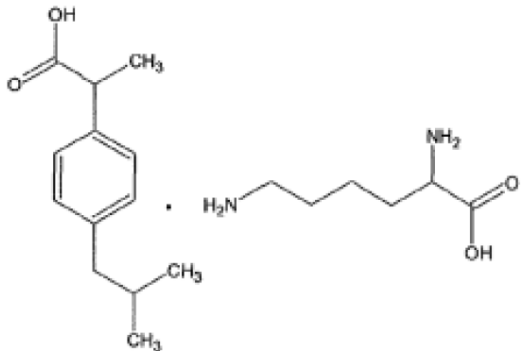
Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with food.

## II.2 Drug Substance

INN: Ibuprofen lysine

Chemical name: (2RS)-2-[4-(2-methylpropyl)phenyl]propanoic acid compound with (2R,S)-2,6-diamino-hexanoic acid Lysine, mono[a-methyl-4-(2-methylpropyl)benzeneacetate]
2-(4-isobutyl-phenyl)-propionic acid; compound with 2,6-diamino-hexanoic acid
α-methyl-4-(2-methylpropyl)-benzene-acetic acid 2,6-diaminohexanoic acid salt
Lysine salt of 2(4-isobutylphenyl) propionic acid

Structure:



Molecular formula: $C_{19}H_{32}N_2O_4$
Molecular weight: 352.48
Description: White to almost white powder.
Solubility Soluble in water, sparingly soluble in methanol and practicaly insoluble in acetone, ether dichloromethane chloride, and ethyl acetate.

Active Substance Master Files (ASMF) have been provided by the active substance manufacturers, covering the manufacture and control of the active substance ibuprofen lysine.

Synthesis of the drug 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.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specification limits. Satisfactory Certificates of Analysis have been provided for all working standards. Batch analysis data are provided that comply with the proposed specification.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with food.

Appropriate stability data have been generated to support a suitable retest period when stored in the proposed packaging.

## II.3. Medicinal Product

### Pharmaceutical Development

The development of the proposed 400mg tablet is based on the earlier development programme for the authorised (PL 00327/0125) ibuprofen lysine salt (200mg ibuprofen equivalent) tablets. The proposed 400mg tablet is directly proportional and is compressed at twice the weight of the 200mg tablet. Therefore, the development pharmaceutics is accepted.

The pharmacopoeial excipients present in the product are povidone, sodium starch glycolate typeA, hypromellose, magnesium stearate and talc. Certificates of Analysis were provided for these excipients.

Excipients not included in a Pharmacopoeia are proprietary Opaspray White M-1-711B and black printing ink, which are controlled to an in-house specification. Certificate of Analysis for Opaspray White and Opacode Black tested by the product manufacturer have been provided.

No materials of animal origin and no genetically modified organisms (GMO) have been used in the preparation of this product.

**Manufacture of the product**
A satisfactory batch formula has been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

**Finished Product Specification**
The finished product specifications proposed are acceptable. Test methods have been described that have been adequately validated. Batch data have been provided and comply with the release specification. Certificates of Analysis have been provided for all working standards used.

**Stability of the Product**
Finished product stability studies were performed in accordance with current guidelines on batches of the finished product in the packaging proposed for marketing. The data from these studies support a shelf-life of 36 months with the storage conditions "Do not store above 25ºC. Store in the original container."

## II.4 Discussion on chemical, pharmaceutical and biological aspects
It is recommended that a Marketing Authorisation is granted for Nurofen Maximum Strength Migraine Pain 684mg Caplets/Nurofen Express 684mg Caplets.

# III NON-CLINICAL ASPECTS
## III.1 Introduction
As the pharmacodynamic, pharmacokinetic and toxicological properties of ibuprofen lysine are well-known, no new non-clinical studies are required and none have been provided. An overview based on the literature review is, thus, appropriate.

The applicant's non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

## III.2 Pharmacology
No new pharmacology data are required for this application and none have been submitted.

## III.3 Pharmacokinetics
No new pharmacokinetic data are required for this application and none have been submitted.

## III.4 Toxicology
No new toxicology data are required for this application and none have been submitted.

## III.5 Ecotoxicity/environmental risk assessment (ERA)
As this product is intended for generic substitution of products that are already marketed, no increase in environmental exposure to ibuprofen lysine is anticipated. Thus, the absence of an ERA is accepted.

## III.6 Discussion on the non-clinical aspects
It is recommended that a Marketing Authorisation is granted for Nurofen Maximum Strength Migraine Pain 684mg Caplets/Nurofen Express 684mg Caplets.

# IV CLINICAL ASPECTS

## IV.1 Introduction

A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of ibuprofen lysine.

The applicant's clinical overview has been written by an appropriately qualified person and is considered acceptable.

## IV.2 Pharmacokinetics

In support of this application, the applicant submitted the two bioavailability studies.

The table below shows two bioavailability studies:

| **Product used in Volunteer Studies (all strengths are shown as ibuprofen equivalent)** | **Design of Bioavailability study in human volunteers** |
|---|---|
| Ibuprofen lysine salt 400mg equivalent tablet (test)<br>Nurofen 200mg tablets (Pivotal) | Open, randomised, single-dose, two-way, crossover<br>1x400mg test v/s<br>2x200mg Nurofen tablets |
| Ibuprofen lysine salt 200mg equivalent tablets (test)<br>Dolormin ibuprofen lysine salt 200mg equivalent tablet<br>Nurofen 200mg tablets | Open, randomised, single-dose, three-way, crossover<br>2x200mg test v/s<br>2x200mgNurofen v/s<br>2x200mg Dolormin tablets |

In the first study the Ibuprofen lysine salt 400mg equivalent tablets used are identical to the proposed formulation except the tablets are unprinted. Nurofen tablets are from the UK market.

In the second study the Ibuprofen lysine salt 200mg equivalent tablets used were of the same granulation mix as for 400mg equivalent tablets but compressed to a lower weight. The Nurofen tablets were from the UK market and Dolormin tablets were from the German market.

### Study 1

The pivotal study was conducted in September 1998.

The trial was an open, randomised, single-dose, two-way crossover study in healthy volunteers comparing Ibuprofen lysine 684mg tablets and 2x 200mg Nurofen tablets, marketed in UK.

Blood samples were taken 10, 20, 25, 30, 35, 40, 45, 50, 60, 70, 80 and 90 minutes and 2, 2.5, 3, 4, 6, 8 and 12 hour post-dose. The wash out period of 7 days is accepted.

The plasma samples were analysed by validated HPLC assay method.

The pharmacokinetic parameters were determined from the log transformed data and are summarised in the table below:

| | **Ibuprofen 400mg Lysine tablets** | **Nurofen 2x200mg** | **Ratio of Ibuprofen Lysine/Nurofen** | **90% CI** |
|---|---|---|---|---|
| **Geometric means** | | | | |
| Cmax (ug/ml) | 47.1 | 38.2 | 1.23 | 1.14-1.34 |
| AUCo-t (h.ug/ml) | 112.6 | 112.2 | 1.00 | 0.96-1.05 |
| AUCo-∞ (h.ug/ml) | 117.0 | 116.6 | 1.00 | 0.96-1.05 |

| | | | | |
|---|---|---|---|---|
| Tmax (h) | 0.63 | 1.17 | - | - |

The data show that the AUC values are within the EU guideline for bioequivalence (90% confidence interval 80.00-125.00% for log transformed data), indicating the extent of absorption from the two products to be equivalent.

The rate of absorption is faster for the Ibuprofen 400mg Lysine tablets than from the Nurofen 200mg tablets. The 90% Confidence Interval for Cmax is outside the 80.00-125.00% range, indicating non-equivalence for the rate of absorption, with faster Tmax and larger Cmax.

## Study 2

This study was conducted in September 1997.

The trial was an open, randomised, single-dose, three-way crossover study in healthy volunteers comparing 2x200mg Ibuprofen lysine film-coated tablets, 2x 200mg Nurofen standard tablets and 2x200mg Dolormin (Ibuprofen lysine) tablets.

Blood samples were taken 10, 20, 25, 30, 35, 40, 45, 50, 60, 70, 80 and 90 minutes and 2, 2.5, 3, 4, 6, 8 and 12 hour post-dose. The wash out period of 3-7 days is accepted.

The plasma samples were analysed by validated HPLC assay method.

The pharmacokinetic parameters were determined from the log transformed data and are summarised in the table below:

| | **Dolormin 2x200mg** | **Ibuprofen Lysine 2X200mg** | **Nurofen Standard 2x200mg** |
|---|---|---|---|
| **Geometric means** | | | |
| Cmax (ug/ml) | 48.463 | 48.483 | 36.173 |
| AUCT (h.ug/ml) | 105.986 | 104.488 | 108.56 |
| AUCI (h.ug/ml) | 111.188 | 109.246 | 114.120 |
| Tmax (h) | 0.5 | 0.583 | 1.33 |

| Article I. Ratio | | | | **90% Confidence Interval** | | |
|---|---|---|---|---|---|---|
| | **Dolormin/ Nurofen** | **Lysine/ Nurofen** | **Lysine/ Dolormin** | **Dolormin/ Nurofen** | **Lysine/ Nurofen** | **Lysine/ Dolormin** |
| Cmax (ug/ml) | 1.33974 | 1.34028 | 1.00041 | 1.24881-1.43728 | 1.24932-1.43787 | 0.93251-1.073225 |
| AUCT (h.ug/ml) | 0.97629 | 0.96249 | 0.98587 | 0.94116-1.01273 | 0.92786-0.99842 | 0.95040-1.02266 |
| AUCI (h.ug/ml) | 0.97431 | 0.95729 | 0.98253 | 0.94091-1.00889 | 0.92448-0.99127 | 0.94886-1.01741 |

The data indicate that ibuprofen lysine and Dolormin have similar extents of absorption of ibuprofen as Nurofen, with 90% CI for AUC within the 0.800-1.2500 equivalence range defined in the EU guidelines.

The rate of absorption of ibuprofen from ibuprofen lysine and Dolormin was significantly faster than the standard Nurofen, resulting in significantly higher Cmax after ibuprofen Lysine and Dolormin, than the standard Nurofen tablets.

The pharmacokinetic profiles of ibuprofen lysine and Dolormin tablets are similar but different to the standard Nurofen tablets with respect to the rate of absorption. The extent of absorption for all three formulations tested was equivalent.

**Conclusions on pharmacokinetics**
It is well known that ibuprofen salts, such as ibuprofen lysine, are more soluble in water and absorption of ibuprofen has been shown to be more rapid following oral administration. The results of the bioequivalence studies are as expected and Ibuprofen Lysine tablets 684 mg were bioequivalent to standard Ibuprofen acid 400mg with regard to extent of absorption. The higher value for C max achieved by ibuprofen lysine is still within the therapeutic window for ibuprofen and is consistent with other formulations of Ibuprofen lysine marketed in the EU, including the UK.

## IV.3 Pharmacodynamics
No new pharmacodynamic data were submitted and none are required for applications of this type.

## IV.4 Clinical efficacy
No new data on efficacy have been submitted and none are required for applications of this type.

## IV.5 Clinical Safety
No new data on safety have been submitted and none are required for applications of this type.

## IV.6 Risk Management Plan (RMP) and Pharmacovigilance System
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.

## IV.7 Discussion on the clinical aspects
It is recommended that a Marketing Authorisation is granted for Nurofen Maximum Strength Migraine Pain 684mg Caplets/Nurofen Express 684mg Caplets.

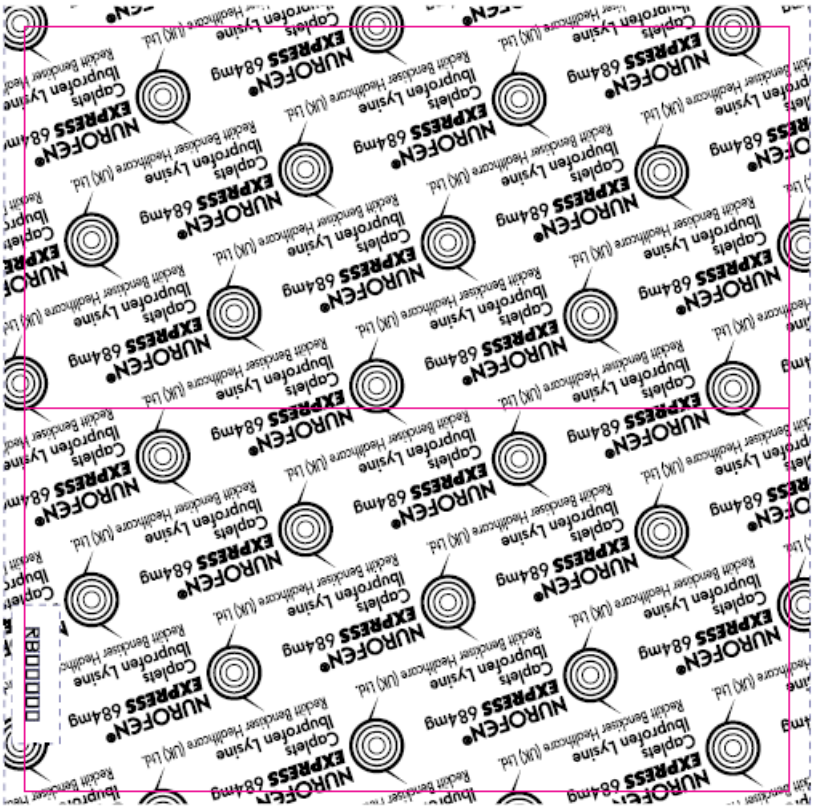
# V User consultation
The package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner.

# VI Overall conclusion, benefit/risk assessment and recommendation
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with ibuprofen lysine is considered to have demonstrated the therapeutic value of the compounds. The benefit-risk is, therefore, considered to be positive.

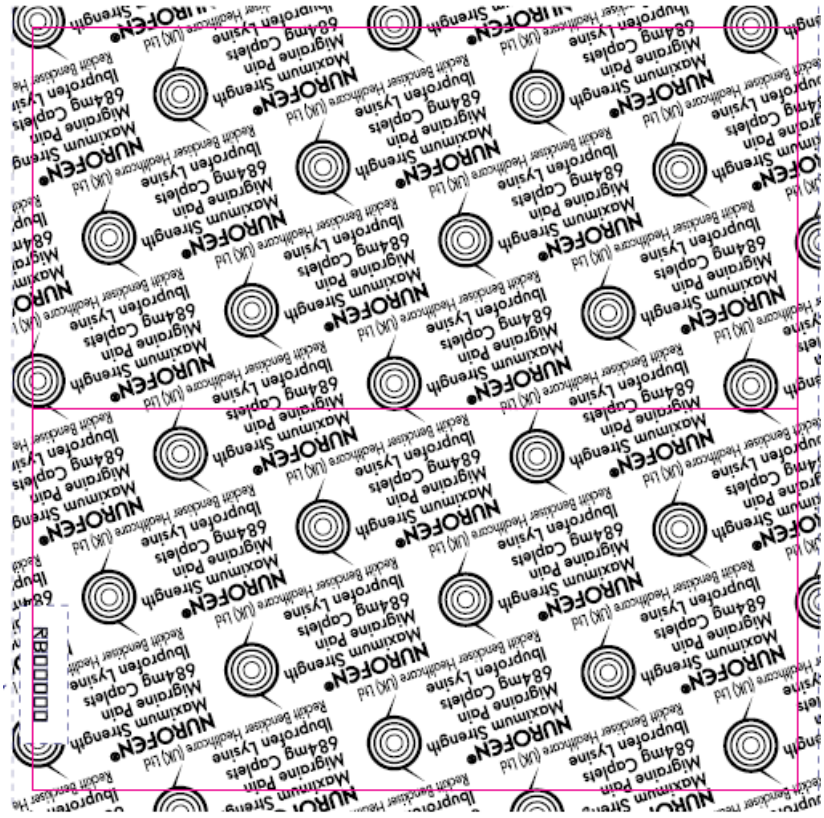
**Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels**
In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on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

The approved labels are shown below:


Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 4AQ.
PL 00063/0384
P
KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN.
Store below 25°C.
Store in the original pack.
5 000158 102132
Nurofen Express 684mg Caplets
FOR RELIEF FROM:
• Migraine pain • Headache
DO NOT TAKE IF YOU:
• have ever had a stomach ulcer, perforation or bleeding
• are allergic to ibuprofen (or anything else in this medicine), aspirin or other related painkillers
• are taking other NSAID painkillers, or aspirin with a daily dose above 75mg
• are in the last 3 months of pregnancy.
SPEAK TO A PHARMACIST/DOCTOR BEFORE TAKING IF YOU:
• have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems or are dehydrated
• are a smoker • are pregnant
DOSAGE:
For oral administration and short-term use only.
Adults, the elderly and children & adolescents between 12 and 18 years: Swallow 1 caplet with water, up to three times a day as required. Leave at least 4 hours between doses. Do not take more than 3 caplets in any 24 hours. Do not give to children under 12 years of age.
Children and adolescents between 12 and 18 years:
If the product is required for more than 3 days, or if symptoms worsen a doctor should be consulted. Adults: If the product is required for more than 10 days, or if symptoms worsen a doctor should be consulted.
WARNING: Do not take more medicine than the label tells you to.
Read the enclosed leaflet carefully before use.
Each caplet contains: Ibuprofen Lysine 684mg (equivalent to Ibuprofen 400mg)
NUROFEN®
EXPRESS 684mg Caplets
MAX STRENGTH
NUROFEN®
EXPRESS
684mg Caplets
Ibuprofen Lysine
Targets Pain Fast
N684
24 Caplets
RB00000
LOT:
EXP:


NUROFEN
EXPRESS 684mg
Caplets
Ibuprofen Lysine
Reckitt Benckiser Healthcare (UK) Ltd.


Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 4AQ.
PL 00063/0384
P
KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN.
Store below 25°C.
Store in the original pack.
5 000167 093742 2
Nurofen Maximum Strength Migraine Pain 684mg Caplets
FOR RELIEF FROM:
• Migraine pain • Headache
DO NOT TAKE IF YOU:
• have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
• are allergic to Ibuprofen or any other ingredient of the product, aspirin or other related painkillers
• are taking other NSAID painkillers or aspirin with a daily dose above 75mg
SPEAK TO A PHARMACIST/DOCTOR BEFORE TAKING IF YOU:
• have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems or are dehydrated.
• are a smoker • are pregnant
DOSAGE:
For oral administration and short-term use only.
Adults, the elderly and children & adolescents between 12 and 18 years:
Swallow 1 caplet with water up to three times a day as required. Leave at least 4 hours between doses. Do not take more than 3 caplets in any 24 hours. Do not give to children under 12 years of age.
Children and adolescents between 12 and 18 years: If the product is required for more than 3 days, or if symptoms worsen a doctor should be consulted. Adults: If the product is required for more than 10 days, or if symptoms worsen a doctor should be consulted.
WARNING: Do not take more medicine than the label tells you to.
Read the enclosed leaflet carefully before use.
Each caplet contains: Ibuprofen Lysine 684mg
(equivalent to Ibuprofen 400mg)
NUROFEN
MAXIMUM STRENGTH
MIGRAINE PAIN
684mg Caplets
NUROFEN
MAXIMUM STRENGTH
MIGRAINE PAIN
684mg Caplets
RB00000
LOT:
EXP:
NUROFEN
MAXIMUM STRENGTH
MIGRAINE PAIN
684mg Caplets
Ibuprofen Lysine
Targeted Rapid Relief
N684
12 Caplets
Ink & varnish free area


NUROFEN
Maximum Strength
Migraine Pain
Ibuprofen Lysine
684mg Caplets

## Table of content of the PAR update

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

| Scope | Procedure number | Product Information affected | Date of start of the procedure | Date of end of procedure | Approval/ non approval | Assessment report attached |
|---|---|---|---|---|---|---|
| To update section 5.1 of the SmPC in line with the Reference product. The patient information leaflet and labelling remains unaffected | PL 00063/0384 - 0023 | SmPC | 23/06/2017 | 12/10/2017 | Approval | Y (Annex 1) |

## Annex 1

| | |
|---|---|
| **Reference:** | PL 00063/0384 - 0023 |
| **Product:** | Nurofen Maximum Strength Migraine Pain 684mg Caplets<br>Nurofen Express 684mg Caplets |
| **Marketing Authorisation Holder:** | Reckitt Benckiser Healthcare (UK) Limited |
| **Active Ingredient(s):** | Ibuprofen lysine |

**Reason:**
To update section 5.1 of the SmPC in line with the Reference product. The patient information leaflet and labelling remains unaffected.

**Supporting Evidence**
Revised SmPC fragments and an updated Clinical Overview have been provided.

**Evaluation**
The amended sections of the SmPC are satisfactory.
Adequate clinical information has been provided.

The current SmPC is available on the MHRA website.

**Decision**
Approved on 12 October 2017.