



Medicines & Healthcare products  
Regulatory Agency



## **Public Assessment Report**

**UKPAR**

**Ibuprofen 800mg PR tablets  
(ibuprofen)**

**UK Licence Number: PL 00037/0676**

**Abbott Laboratories Limited**

## LAY SUMMARY

### **Ibuprofen 800mg PR tablets (ibuprofen)**

This is a summary of the Public Assessment Report (PAR) for Ibuprofen 800mg PR tablets (PL 00037/0676). This medicinal product will be referred to as Ibuprofen Tablets in the remainder of the report for ease of reading.

This summary explains how Ibuprofen Tablets was assessed and its authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

For practical information about using Ibuprofen Tablets, patients should read the Patient Information Leaflet (PIL) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website or contact their doctor or pharmacist.

#### **What are Ibuprofen Tablets and what are they used for?**

This medicine is the same as Brufen Retard 800 mg Tablets (PL 46302/0010) which has already been authorised. The company (Mylan Products Limited) that makes Brufen Retard 800 mg Tablets (PL 46302/0010) has used its scientific data as a basis for the grant of an identical licence for Ibuprofen Tablets (informed consent).

Ibuprofen Tablets can be used to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of the spine, ankylosing spondylitis, swollen joints, frozen shoulder, bursitis, tendinitis, tenosynovitis, lower back pain, sprains and strains.

Ibuprofen Tablets can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine.

#### **How do Ibuprofen Tablets work?**

Ibuprofen (the active substance in this medicine) belongs to a group of medicines called anti-inflammatory pain killers. It can be used to relieve pain and inflammation.

#### **How are Ibuprofen Tablets used?**

Ibuprofen 800mg PR tablets are prolonged-release tablets taken by mouth (orally).

The patient should always take this medicine exactly as his/her doctor has advised. The patient should check with his/her doctor or pharmacist if unsure.

Ibuprofen Tablets are taken with or after food, with a glass of water. Ibuprofen Tablets should be swallowed whole and not chewed, broken, crushed or sucked to help prevent discomfort in the mouth or irritation in the throat.

Ibuprofen is **NOT** suitable for children under 12 years of age.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration and the duration of treatment.

### **How have Ibuprofen Tablets been studied?**

Ibuprofen Tablets (PL 00037/0676) are considered identical to previously authorised Brufen Retard 800 mg Tablets (PL 46302/0010) (Mylan Products Limited), with the same benefits and risks. No new studies have been provided for Ibuprofen Tablets (PL 00037/0676), but reference is made to the studies Brufen Retard 800 mg Tablets (PL 46302/0010).

### **What are the possible side effects of Ibuprofen Tablets?**

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

The application for Ibuprofen Tablets is considered to be identical to the previously authorised application for Brufen Retard 800 mg Tablets (Mylan Products Limited) (PL 46302/0010) with the same benefits and risks.

For a full list of all the side effects reported with Ibuprofen Tablets see section 4 of the patient information leaflet (PIL), available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

For the full list of restrictions, see the patient information leaflet (PIL).

### **Why are Ibuprofen Tablets approved?**

No new or unexpected safety concerns arose from this application. The MHRA, therefore, considered that the benefits of Ibuprofen Tablets outweigh their risks; and the grant of a marketing authorisation was recommended.

### **What measures are being taken to ensure the safe and effective use of Ibuprofen Tablets?**

A Risk Management Plan (RMP) has been developed to ensure that Ibuprofen Tablets are used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics (SmPC) and the patient information leaflet (PIL) for Ibuprofen Tablets, including the appropriate precautions to be followed by patients.

Known side-effects are continuously monitored. Furthermore, new safety signals reported by patients and healthcare professionals will be monitored and reviewed continuously, as well.

### **Other information about Ibuprofen Tablets**

The UK granted a marketing authorisation for Ibuprofen 800mg PR tablets on 04 October 2017. The full PAR for Ibuprofen Tablets follows this summary. For more information about treatment with Ibuprofen Tablets, read the patient information leaflet (PIL) or the patient should contact their doctor or pharmacist. This summary was last updated in December 2017.

**Ibuprofen 800mg PR tablets  
PL 00037/0676**

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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 Ibuprofen 800mg PR tablets, (PL 00037/0676), could be approved. This product is a Prescription-Only Medicine (legal status POM) indicated for:

- Its analgesic and anti-inflammatory effects in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid (seronegative) arthropathies.
- In the treatment of non-articular rheumatic conditions, Ibuprofen is indicated in periarticular conditions such as frozen shoulder (capsulitis), bursitis, tendinitis, tenosynovitis and low back pain; Ibuprofen can also be used in soft tissue injuries such as sprains and strains.
- Ibuprofen is also indicated for its analgesic effect in the relief of mild to moderate pain such as dysmenorrhoea, dental and post-operative pain and for symptomatic relief of headache, including migraine headache.

These applications were made under Article 10c of Directive 2001/83/EC, as amended, claiming to be identical to the cross-reference products Brufen Retard 800 mg Tablets (PL 46302/0010).

### Ibuprofen 800mg PR tablets

The Applicant makes reference to a national marketing authorisation granted to Mylan Products Limited for Brufen Retard 800 mg Tablets (PL 46302/0010) which was transferred to this marketing authorisation holder on 16 August 2016 by change of ownership. Prior to this, the product has undergone multiple changes of ownership, including registration to BPG Products Limited (PL 43900/0010) from 16 April 2015, Abbott Laboratories Limited (PL 00037/0338) from 31 December 2001 and Knoll Pharma Limited from 01 April 1993.

No new non-clinical or clinical studies were conducted, which is acceptable given that the application is for a product which is identical to a product that has been granted a marketing authorisation in the UK.

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.

A satisfactory summary of the pharmacovigilance system and risk management plan has been provided with these applications.

National Marketing Authorisations were granted in the UK on 04 October 2017.

## II QUALITY ASPECTS

**LICENCE NO(S):** PL 00037/0676  
**PROPRIETARY NAMES:** Ibuprofen 800mg PR tablets  
**ACTIVE(S):** ibuprofen  
**COMPANY NAME:** Abbott Laboratories Limited  
**E.C. ARTICLE:** Article 10c of Directive 2001/83/EC, as amended  
**LEGAL STATUS:** Prescription-Only Medicine (legal status POM)

### II.1 INTRODUCTION

This is a simple, informed consent application for Ibuprofen 800mg PR tablets, submitted under Article 10c of Directive 2001/83/EC, as amended.

### II.2 Medicinal Product Name

The following product name is proposed: Ibuprofen 800mg PR tablets. The product has been named in line with current requirements.

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

Ibuprofen 800mg PR tablets contain 800mg of the active substance ibuprofen.

The route of administration is oral.

#### Ibuprofen 800mg PR tablets:

The finished products are packaged in opaque, PVC film coated / polyvinylidene chloride / aluminium lidding foil blisters. The blisters are packed into cartons containing 56 tablets.

Not all pack sizes may be marketed, however, the marketing authorisation holder has agreed to provide mock-ups of any pack size to the relevant regulatory authorities before marketing.

The proposed shelf-life is 3 years with the storage conditions, 'Do not store above 25°C, store in the original package'. The proposed packaging and shelf-life are consistent with the details registered for the cross-reference product.

#### **Legal status**

On approval, this product will be available as a prescription-only medicine (POM).

#### **Marketing authorisation holder/Contact Persons/Company**

Abbott Laboratories Limited, Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, SL6 4XE, UK

#### **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 composition is consistent with the details registered for the cross-reference product.

**Manufacturing process**

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

**Finished product/shelf-life specification**

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

**Drug substance specification**

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

**TSE Compliance**

None of the excipients contain materials of animal or human origin.

No genetically modified organisms (GMO) have been used in the preparation of these products.

**Expert Report**

The applicant has included expert reports in Module 2 of these applications. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

**Product Name and Appearance**

See section 'II.3. Medicinal Product Name' for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

**Summary of Product Characteristics (SmPC)**

The proposed SmPCs are consistent with the details registered for the cross-reference product.

**II.3 Discussion on chemical, pharmaceutical and biological aspects**

The grant of a marketing authorisation is recommended.

**III NON-CLINICAL ASPECTS****Introduction**

No new non-clinical data have been supplied with this application and none are required for an application of this type.

**Ecotoxicity/Environmental Risk Assessment (ERA)**

Since this product will be used in substitution for other products that are currently on the market, no increase in environmental exposure is anticipated. An Environmental Risk Assessment (ERA) is, therefore, not deemed necessary.

**Discussion on the non-clinical aspects**

The grant of a marketing authorisation is recommended.

## IV CLINICAL ASPECTS

### Introduction

No new clinical data have been supplied with this application and none are required for an application of this type.

The SmPC and PIL is consistent with those of the cross-reference product.

The Marketing Authorisation Holder (MAH) 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.

The Qualified Person (QP) responsible for pharmacovigilance is stated and their Curriculum Vitae (CV) is included.

### Risk Management Plan (RMP)

The Marketing Authorisation Holder (MAH) has submitted a Risk Management Plan (RMP), in accordance with the requirements of Directive 2001/83/EC, as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to the use of this product. A summary of safety concerns, as approved in the RMP, is listed below:

Important identified risks	<ul style="list-style-type: none"> <li>• Gastrointestinal bleeding, ulceration and perforation (and related complications)</li> <li>• Cardiovascular risk</li> <li>• Serious skin reactions</li> </ul>
Important potential risks	<ul style="list-style-type: none"> <li>• Renal disorders</li> </ul>
Potential interaction as important potential risk	<ul style="list-style-type: none"> <li>• Interaction with low-dose aspirin</li> </ul>
Missing information	<ul style="list-style-type: none"> <li>• Treatment of Patent Ductus Arteriosus</li> </ul>

Routine pharmacovigilance and routine risk minimisation are proposed for all safety concerns.

### Discussion on the clinical aspects

The grant of a marketing authorisation is recommended.

## V User consultation

The company makes reference to a user consultation with target patient groups on the essentially identical patient information leaflet (PIL) for Brufen Retard. This is acceptable.

**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 product is identical to the respective cross-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.

In accordance with Directive 2010/84/EU, the current approved UK versions of the SmPC and PIL for this product are available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

The current approved labels for Ibuprofen 800mg PR tablets are presented on the following pages:



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 <b>IBUPROFEN</b> 800mg prolonged release tablets Abbott Laboratories Ltd. N950 <b>Monday</b>	 <b>IBUPROFEN</b> 800mg prolonged release tablets Abbott Laboratories Ltd. N950 <b>Tuesday</b>	 <b>IBUPROFEN</b> 800mg prolonged release tablets Abbott Laboratories Ltd. N950 <b>Wednesday</b>
Each sustained-release tablet contains 800mg ibuprofen		
Take two tablets each evening as a single dose, or as prescribed		
 <b>IBUPROFEN</b> 800mg prolonged release tablets Abbott Laboratories Ltd. N950 <b>Friday</b>	 <b>IBUPROFEN</b> 800mg prolonged release tablets Abbott Laboratories Ltd. N950 <b>Saturday</b>	 <b>IBUPROFEN</b> 800mg prolonged release tablets Abbott Laboratories Ltd. N950 <b>Sunday</b>

  

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## Table of content of the PAR update

Steps taken after the initial procedure with an influence on the Public Assessment  
Report (Type II variations, PSURs, commitments)

<b>Date submitted</b>	<b>Application type</b>	<b>Scope</b>	<b>Outcome</b>