# Lay Summary

**Ibuprofen 200 mg Film-coated Tablets**

**PL 00071/0662**

**UKPAR**

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Ibuprofen 200 mg Film-coated Tablets

PL 00071/0662

LAY SUMMARY

On 7th February 2013, the MHRA granted a Marketing Authorisation (licence) for the medicinal product Ibuprofen 200 mg Film-coated Tablets (PL 00071/0662). This is a general sale list medicine (GSL).

Ibuprofen 200 mg Film-coated Tablets are used for the relief of headaches including tension headaches and migraine. They can also be used for rheumatic and muscular pains, period pains, backache, neuralgia, toothache and to relieve the fever and other symptoms of cold and flu.

The active ingredient is ibuprofen, which belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This group of medicines relieves pain, reduces inflammation and lowers temperature when you have a fever.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Ibuprofen 200 mg Film-coated Tablets outweigh the risks; hence a Marketing Authorisation has been granted.
Ibuprofen 200 mg Film-coated Tablets

PL 00071/0662

SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare Products Regulatory Agency (MHRA) granted a Marketing Authorisation (licence) for the medicinal product Ibuprofen 200 mg Film-coated Tablets (PL 00071/0662) to SmithKline Beecham (SWG) Limited, trading as GlaxoSmithKline Consumer Healthcare, on 7th February 2013.

This is a GSL medicine used for the relief of headaches including tension headaches and migraine, rheumatic and muscular pains, period pains, backache, neuralgia, toothache, feverishness and symptoms of colds and flu.

This application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, as amended. This product is cross referring to Hedex Ibuprofen 200 mg Tablets (PL 00071/0313), which was originally authorised to Smithkline Beecham (SWG) Limited on 14th August 1989.

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 master file system (PMFS) has been provided with this application and is satisfactory.

No environmental risk assessment (ERA) has been undertaken, as this is not considered necessary. The introduction of Ibuprofen 200 mg Tablets to the environment through use and proper disposal raises no significant environmental concerns. The applicant’s justification for absence of ERA is satisfactory.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00071/0662
PROPRIETARY NAME: Ibuprofen 200 mg Film-coated Tablets
COMPANY NAME: SmithKline Beecham (SWG) Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: GSL

1 INTRODUCTION
This is an informed consent application for Ibuprofen 200 mg Film-coated Tablets, submitted under Article 10c of Directive 2001/83/EC, as amended. The application cross-refers to Hedex Ibuprofen 200 mg Tablets (PL 00071/0313), which was originally authorised to Smithkline Beecham (SWG) Limited on 14th August 1989. The current application is considered valid.

2 MARKETING AUTHORISATION APPLICATION (MAA)
2.1 Name(s)
The proposed name of the product is Ibuprofen 200 mg Film-coated Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The product is a tablet for oral use and contains 200mg ibuprofen.

The tablets are packed in polyvinylchloride (PVC) /Aluminium foil blisters in cardboard cartons containing 12 or PVC /Aluminium foil blisters in a round, wallet style pack containing 12 tablets.

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

The proposed shelf-life is 36 months with storage condition “Store below 25°C” has been set.

The shelf-life and storage condition are identical to those for the cross-reference product and are satisfactory.

2.3 Legal status
This product is a General Sale List (GSL) medicine.

2.4 Marketing Authorisation Holder/Contact Persons/Company
The proposed Marketing Authorisation holder is SmithKline Beecham (SWG) Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom

2.5 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.
2.6 **Qualitative and quantitative composition**
The proposed compositions are consistent with the details registered for the cross-reference product.

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

2.8 **Finished product specifications**
The proposed finished product specifications, at release and shelf-life, are in line with the details registered for the cross-reference product.

2.9 **Drug substance specification**
The proposed drug substance specification conforms to the current European Pharmacopoeia monograph for ibuprofen and is in-line with that for the cross-reference product.

An European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability for the manufacturer of ibuprofen has been provided. The active substance manufacturer is the same as that for the cross-reference product.

2.10 **TSE Compliance**
Lactose is the only material of human or animal origin used in the manufacture of this product but it does not present a TSE-risk. The applicant has confirmed that the magnesium stearate used in the tablet is of vegetable origin. This is consistent with the reference product.

2.11 **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 cross-reference product Hedex Ibuprofen 200 mg Tablets (PL 00071/0313).

3. **EXPERT REPORTS**
The applicant cross-referes to the data for cross-reference product Hedex Ibuprofen 200 mg Tablets (PL 00071/0313), to which it claims to be identical. This is acceptable. The applicant has included expert reports in 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.

4. **PRODUCT NAME & APPEARANCE**
See 2.1 for details of the proposed product name. The appearance of the product is identical to that of the cross-reference product.

5. **SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**
The proposed SmPC is consistent with the details registered for the cross-reference product.
6. PATIENT INFORMATION LEAFLET (PIL)/LABELLING
The Marketing Authorisation Holder has committed to submit full colour mock-ups of the PIL and labelling together with results of consultations with target patient groups, to the relevant regulatory authorities, for approval before the product is commercially marketed.

7. CONCLUSION
The data submitted with the application are acceptable. The grant of marketing authorisation is recommended.
NON-CLINICAL ASSESSMENT

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

No new clinical data have been supplied with this application and none are required for applications of this type.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application are consistent with those previously assessed for the cross-reference product and, as such, have been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY
This application is identical to the previously granted application for Hedex Ibuprofen 200 mg Tablets (PL 00071/0313), authorised to Smithkline Beecham (SWG) Limited on 14th August 1989.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory and consistent with those for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with ibuprofen is considered to have demonstrated the therapeutic values of the compound. The risk benefit is, therefore, considered to be positive.
## STEPS TAKEN FOR ASSESSMENT

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<td>1</td>
<td>The MHRA received the Marketing Authorisation application on 17th October 2011</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application is valid on 16th November 2011</td>
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<td>3</td>
<td>Following assessment of the application the MHRA requested further information on 12th January 2012, 1st August 2012 and 6th February 2013</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s request, providing further information on 4th July 2012, 30th October 2012 and 7th February 2013</td>
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<td>5</td>
<td>The application was determined on 7th February 2013</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) for products that have been granted Marketing Authorisations at a national level are available on the MHRA website.
PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU the Patient Information Leaflets (PILs) for products that have been granted Marketing Authorisations at a national level are available on the MHRA website.
LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. NAME OF THE MEDICINAL PRODUCT

Ibuprofen 200 mg Film-coated Tablets

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 200 mg Ibuprofen.

3. LIST OF EXCIPIENTS

Also contains lactose.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet

12 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Please read the enclosed leaflet carefully before taking these tablets.

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

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Warning. Do not exceed the stated dose.
DO NOT USE:
• if you are allergic to ibuprofen or aspirin.
• if you have or have ever had a stomach ulcer or other stomach disorders.

CONSULT YOUR DOCTOR:
• before taking, if you are allergic to or are taking any other painkillers.
• before taking, if you suffer from asthma or are pregnant.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Store below 25°C.

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9QS, U.K.

12. MARKETING AUTHORISATION NUMBER(S)

PL 00071/0662

13. BATCH NUMBER

BN:

14. GENERAL CLASSIFICATION FOR SUPPLY

GSL
15. INSTRUCTION ON USE

Effective relief for headaches.

**Ibuprofen 200 mg Film-coated Tablets** have been formulated for effective pain relief. The tablets are coated and shaped to be easy to swallow.

**USES:** Ibuprofen 200 mg Film-coated Tablets are suitable for the relief of headaches including tension headaches and migraine. They are also useful for the effective relief of rheumatic and muscular pain, period pains, backache, neuralgia, toothache, feverishness and the symptoms of colds and flu.

**DOSAGE:** Adults (including the elderly) and children 12 years and over: Take one or two tablets with water, up to 3 times a day, preferably with or after food. Do not take more often than every 4 hours. Do not take more than six tablets in any 24-hour period. Do not give to children under 12 years. If your headaches become persistent, see your doctor. If symptoms persist consult your doctor.

16. INFORMATION IN BRAILLE

Ibuprofen 200 mg Film-coated Tablets
## MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

| Blister |

### 1. NAME OF THE MEDICINAL PRODUCT

Ibuprofen 200 mg Film-coated Tablets

### 2. NAME OF THE MARKETING AUTHORIZATION HOLDER

GlaxoSmithKline Consumer Healthcare

### 3. EXPIRY DATE

<Printed at the time of manufacture>

### 4. BATCH NUMBER

<Printed at the time of manufacture>

### 5. OTHER