IBUPROFEN 200MG TABLETS
PL 00063/0573

UKPAR

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IBUPROFEN 200MG TABLETS
PL 00063/0573

LAY SUMMARY

The Medicines Healthcare products Regulatory Agency (MHRA) granted Reckitt Benckiser Healthcare (UK) Limited a Marketing Authorisation for the medicinal product Ibuprofen 200mg Tablets (PL 00063/0573) on 26th September 2008. The name Ibuprofen 200mg Tablets is a temporary name and the product will not be marketed until the name is changed by variation. This product is a general sales list (GSL) medicine and is available to the general public without prescription. Ibuprofen 200mg Tablets is used for relief of headaches, migraine, backache, period pain, dental pain, neuralgia, muscular pain, rheumatic

Ibuprofen 200mg Tablets contains the active ingredient ibuprofen, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling and high temperature.

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

IBUPROFEN 200MG TABLETS
PL 00063/0573

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a marketing authorisation for the medicinal product Ibuprofen 200mg Tablets (PL 00063/0573) to Reckitt Benckiser Healthcare (UK) Limited on 26th September 2008. The product is a general sale list medicine. The name Ibuprofen 200mg Tablets is a temporary name and the product will not be marketed until the name is changed by variation.

The application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Nurofen 200mg Tablets granted to Crookes Healthcare Limited, PL 00327/0146, approved on 15th July 2003. This in turn is an abridged application and line-extension to the original marketing authorisation Nurofen 200mg Tablets (PL 00327/0004) held by the same Marketing Authorisation Holder granted on 6th May 1983.

No new data were submitted nor was it necessary for this simple application, as the data are identical to that 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) has been generated for it.

The product contains the active ingredient ibuprofen, which is a painkiller, reduces temperature and has anti-inflammatory properties.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 000631/0573
PROPRIETARY NAME: Ibuprofen 200mg Tablets
ACTIVE(S): Ibuprofen
COMPANY NAME: Reckitt Benckiser Healthcare (UK) Limited
E.C. ARTICLE: Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC
LEGAL STATUS: GSL

1. INTRODUCTION

This is a simple, informed consent application for Ibuprofen 200mg Tablets submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, East Yorkshire, HU8 7DS, UK.

The application cross-refers to the applicant's own Marketing Authorisation for Nurofen 200mg Tablets, approved on 15th July 2003. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Ibuprofen 200mg Tablets. The name Ibuprofen 200mg Tablets is a temporary name and will not marketed until the name is changed by variation. This is accepted.

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

The product contains ibuprofen, equivalent to 200mg. The product is stored in blisters composed of either laminate consisting of opaque, white PVC heat-sealed to aluminum foil and further packed into cardboard cartons.

or

laminate consisting of opaque, white PVC PVdC, heat-sealed to aluminum foil and further packed into cardboard cartons containing 2,3,4,5,6,8,10,12,15 and 16 tablets. Not all pack sizes may be marketed. The proposed shelf-life (24 months) with the specific storage conditions, "Do not store above 25°C and "Store in the original pack" this is consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, the product will be available as a general sale list (GSL) medicine which will be available to the general public without a prescription.

2.4 Marketing authorisation holder/Contact Persons/Company

Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, East Yorkshire, HU8 7DS, UK.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is 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 batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference product.

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

2.10 TSE Compliance
A declaration is given that no materials of animal and/or human origin are contained or used in the manufacturing process for the medicinal product. This is consistent with the approved cross-reference product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. 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.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product. The name Ibuprofen 200mg Tablets is a temporary name and will not marketed until the name is changed by variation. This is accepted.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed summary is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

The PIL is in compliance with current guidelines and user testing results have been submitted. The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

Carton and blister

The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the application are acceptable. A Marketing Authorisation should be granted.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

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

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type.

EFFICACY
Ibuprofen is a well known drug and has been used for many years. This application is identical to previously granted application for Ibuprofen 200mg Tablets (PL 00327/0146).

Preclinical, pharmaceutical and clinical expert statements have been provided together with CVs showing the experts are appropriately qualified. The experts confirm that the product is identical in composition, manufacture and pharmaceutical characteristics to the respective reference product and that there are no toxicological or clinical issues.

No new or unexpected safety concerns arise from this application.

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

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product which, in turn, has been shown to be interchangeable with the innovator product. Extensive clinical experience with ibuprofen is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

IBUPROFEN 200MG TABLETS
PL 00063/0573

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 18th July 2008.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 23rd July 2008.
3	Following assessment of the application the MHRA requested further information relating to the quality dossier on 25th July 2008.
4	The applicant responded to the MHRA's requests, providing further information on 5th August 2008.
5	The application was determined on 26th September 2008.

IBUPROFEN 200MG TABLETS
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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

IBUPROFEN 200MG TABLETS
PL 00063/0573

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Ibuprofen 200 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Ibuprofen 200 mg

For a full list of excipients see 6.1.

3 PHARMACEUTICAL FORM
Coated Tablet

A white to off-white, biconvex, round, sugar coated tablet printed 'Nurofen' in black on one face.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
For the relief of migraine-headaches, backache, dental pain, neuralgia and period pains as well as rheumatic and muscular pains.

Nurofen relieves pain and reduces inflammation and temperature as well as relieving headaches and other types of pain. It also relieves cold and flu symptoms.

4.2 Posology and method of administration
For oral administration and short-term use only.

During short-term use, if symptoms persist or worsen the patient should be advised to consult a doctor.

Adults and children over 12 years:

The minimum effective dose should be used for the shortest time necessary to relieve symptoms. If the product is required for more than 10 days, or if the symptoms worsen the patient should consult a doctor.

Initial dose two tablets taken with water, then if necessary, one or two tablets every four hours. Do not exceed six tablets in any 24 hours. Not for use by children under 12 years of age without medical advice.

4.3 Contraindications
Hypersensitivity to ibuprofen or any of the excipients in the product.

Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs.

Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).

History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

Severe heart failure, renal failure or hepatic failure (see section 4.4)

Last trimester of pregnancy

4.4 Special warnings and precautions for use
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).

The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

Respiratory:

Bronchospasm may be precipitated in patients suffering from, or with a history of, bronchial asthma or allergic disease.

Other NSAIDs:

The use of Ibuprofen with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see section 4.5).

SLE and mixed connective tissue disease:

systemic lupus erythematosus as well as those with mixed connective tissue disease (see Section 4.8, Unwanted effects)

Renal:

Renal impairment as renal function may further deteriorate (see sections 4.3 and 4.8).

Hepatic:

Hepatic dysfunction (see sections 4.3 and 4.8)

Cardiovascular and cerebrovascular effects:

Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤1200mg daily) is associated with an increased risk of myocardial infarction.

Impaired female fertility:

There is limited evidence that drugs which inhibit cyclo-oxygenase/prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible upon withdrawal of treatment.

Gastrointestinal:

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated (see section 4.8).

GI bleeding, ulceration or perforation, which can be fatal has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of GI events.

The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 4.3), and in the elderly. These patients should commence treatment on the lowest dose available.

Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin (see section 4.5).

When GI bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn.

Dermatological:

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs (see section 4.8). Patients appear to be at highest risk for these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases within the first month of treatment. Ibuprofen should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

The label will include:

Read the enclosed leaflet before taking this product

Do not take if you:

- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- are allergic to ibuprofen, to any of the ingredients, or to aspirin or other painkillers
- are taking other NSAID pain killers or aspirin with a daily dose above 75mg

Speak to a pharmacist or your doctor before taking if you:

- have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems
- Are a smoker
- Are pregnant

If symptoms persist or worsen, or if new symptoms occur, consult your doctor or pharmacist.

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen (like other NSAIDs) should be avoided used with caution in combination with:

Aspirin unless low-dose aspirin (not above 75mg daily) has been advised by a doctor as this may increase the risk of adverse reactions (see Section 4.4).

Other NSAIDs including cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse effects (see section 4.4)

Ibuprofen should be used in caution in combination with:

Corticosteroids: as these may increase the risk of gastrointestinal ulceration or bleeding (see Section 4.4)

Antihypertensives and diuretics: since NSAIDs may diminish the effects of these drugs. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Anticoagulants. NSAIDs may enhance the effects of anti-coagulants, such as warfarin (See section 4.4).

Ant-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding (see section 4.4).

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

Lithium. There is evidence for potential increase in plasma levels of lithium.

Methotrexate. There is evidence for the potential increase in plasma levels of methotrexate.

Ciclosporin: Increased risk of nephrotoxicity.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

*Quinolone antibiotics:*Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

4.6 Pregnancy and lactation

Whilst no teratogenic effects have been demonstrated in animal experiments, the use of Nurofen, if possible, be avoided during the first 6 months of pregnancy.

During the 3rd trimester, ibuprofen is contraindicated as there is a risk of premature closure of the foetal ductus arteriosus with possible persistent pulmonary hypertension. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child. (See section 4.3 Contraindications).

In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely.

See section 4.4 regarding female fertility.

4.7 Effects on ability to drive and use machines

None expected at recommended dose and duration of therapy.

4.8 Undesirable effects

Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract activity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritis, urticaria, purpura, angioedema and, more rarely, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

The list of the following adverse effects relates to those experienced with NSAIDS at doses available over the counter for short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

Hypersensitivity reactions:

Uncommon: Hypersensitivity reactions with urticaria and pruritis

Very rare: severe hypersensitivity reactions. Symptoms could be facial, tongue and laryngeal swelling, dysponoea, tachycardia, hypotension, (anaphylaxis, angioedema or severe shock).

Exacerbation of asthma and bronchospasm.

Gastrointestinal:

The most commonly observed adverse events are gastrointestinal in nature.

Uncommon: abdominal pain, nausea, dyspepsia

Rare: Diarrhoea, flatulence, constipation and vomiting

Very rare: peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly. Ulcerative stomatitis, gastritis.

Exacerbation of colitis and Crohn's disease (section 4.4).

Nervous System:

Uncommon: Headache

Very rare: Aseptic meningitis – single cases have been reported very rarely.

Renal:

Very rare: Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum and oedema.

Hepatic:

Very rare: liver disorders.

Haematological:

Very rare: Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

Dermatological:

Uncommon: Various skin rashes

Very rare: Severe forms of skin reactions such as bullous reactions including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis can occur.

Immune System:

In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed (see section 4.4).

Cardiovascular and Cerebrovascular

Oedema, hypertension and cardiac failure, have been reported in association with NSAID treatment.

Clinical trial and epidemiological data suggest that the use of NSAIDS (particularly at high doses 2400 mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

4.9 Overdose

In children ingestion of more than 400 mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose is 1.5-3 hours.

Symptoms – Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and the prothrombin time/ INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

Management –

Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: propionic acid derivative

ATC Code: M01A E01

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.

5.2 Pharmacokinetic properties

Ibuprofen is rabidly absorbed following administration and is rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys.

Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after 1 to 2 hours. These times may vary with different dosage forms.

Elimination half-life is approximately 2 hours.

In limited studies, ibuprofen appears in the breast milk in very low concentrations.

5.3 Preclinical safety data

No relevant information, additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Croscarmellose Sodium

Sodium Laurilsulfate

Sodium Citrate

Stearic Acid

Colloidal Anhydrous Silica

Sugar coat ingredients

Carmellose Sodium

French Chalk for Tablets (Talc)

Acacia Spray Dried

Sucrose

Titanium Dioxide

Macrogol 6000

Tablet printing

Opacode S-1-8152 HV Black (solids)[1]

[1]Opacode S-1-8152 HV black contains the following residual materials after application

Shellac USNF 53.504%

Iron oxide black (E172) 44.699%

Soya lecithin 1.788%

Antifoam DC1510 0.009%

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original pack.

6.5 Nature and contents of container

The tablets will be packed in blisters consisting of:

Push through laminate consisting of opaque, white 250 micron PVC heat-sealed to 20 micron aluminium foil

or

Push through laminate consisting of opaque, white 250 micron PVC with 40 gsm PVdC, heat-sealed to 20 micron aluminium foil.

The blisters are contained in a cardboard carton.

2, 3, 4, 5, 6, 8, 10, 12, 15, 16 tablets.

Not all packs will be marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Ltd
Dansom lane,
Hull,
HU8 7DS, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0573

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/09/2008

10 DATE OF REVISION OF THE TEXT

26/09/2008

11 DOSIMETRY (IF APPLICABLE)

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

IBUPROFEN 200MG TABLETS
PL 00063/0573

PATIENT INFORMATION LEAFLET

REMOVABLE

IBUPROFEN
200mg TABLETS

Ibuprofen 200mg

PLEASE READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE. Keep this leaflet. You may want to read it again.

1. WHAT IS THIS MEDICINE AND WHAT IS IT USED FOR?

IBUPROFEN 200mg tablets contain Ibuprofen, 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.

IBUPROFEN 200mg tablets are for the effective relief of:

- headaches, backache, period pain, dental pain, neuralgia (nerve pain) and migraine
- muscle pain, rheumatic pain
- symptoms of colds and flu, high temperature (fever)

2. BEFORE TAKING THIS MEDICINE

You should not take IBUPROFEN 200mg tablets if:

- you have had an allergic reaction to aspirin, ibuprofen, any other NSAIDs or any of the ingredients (see section 6 for further information).
- you have had a worsening of asthma, allergic rash or an itchy runny nose when taking ibuprofen, aspirin or similar medicines.
- you have had severe liver, kidney or heart problems.
- you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding.
- you are under 12 years of age.

Ask your doctor before taking IBUPROFEN 200mg tablets if:

- you have high blood pressure.
- you have asthma or have suffered from asthma.
- you know you have kidney, heart, bowel or liver problems.
- you have a condition know as Systemic Lupus Erythematosus (SLE) - an illness which affects your immune system. It causes joint pain, skin changes and problems with other parts of your body.
- you have been told to limit the amount of sodium in your diet.
- you are taking any medication, especially:
  - other pain relievers or products containing aspirin, ibuprofen or other NSAIDS.
  - Medicines for high blood pressure e.g. water tablets (diuretics).
  - Medicines for heart conditions (cardiac glycosides).
  - Medicines for thinning the blood (anti-coagulants).
  - low dose 75mg aspirin (one a day).
  - corticosteriods.
  - Mifepristone (a medicine which induces labour).
  - Medicines which change the immune system (ciclosporin and tacrolimus).
  - Methotrexate (a medicine for cancer).
  - Medicines for depression (lithium and selective serotonin uptake inhibitors).
  - Quinolone antibiotics and Zidovudine (medicines used to treat bacterial and viral infections).
- you are pregnant or breast-feeding.
- IBUPROFEN 200mg tablets belong to a group of medicines, which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that IBUPROFEN 200mg tablets, used occasionally will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Medicines such as IBUPROFEN 200mg tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses

and prolonged treatment. Do not exceed the recommended dose or take for longer than necessary to control the symptoms (10 days).

- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

3. HOW TO TAKE THIS MEDICINE

This product is intended for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms. You should not take for longer than 10 days unless your doctor tells you to.

Adults and children of 12 years and older:

Take 2 tablets with water, then if necessary take 1 or 2 tablets every 4 hours. Leave at least 4 hours between doses. Do not exceed 6 tablets in 24 hours.
Not suitable for children under 12 years.
If symptoms persist or worsen, or if new symptoms occur, consult your doctor or pharmacist.
If you take too many tablets by mistake, contact your doctor or pharmacist straight away. If symptoms persist or if the pain or fever worsens, or if new symptoms occur, consult your doctor or pharmacist.

4. POSSIBLE SIDE-EFFECTS

IBUPROFEN 200mg tablets is generally well tolerated by the majority of people, however, the following side effects may occur: stomach discomfort or pain, nausea, stomach ulcer, black tarry stools, worsening of asthma, unexplained wheezing or shortness of breath, liver and kidney problems, headache, dizziness and hearing disturbance and rarely skin rash, itching, peeling, unusual bleeding, easy bruising or facial swelling, high temperature or fever, sore throat or mouth ulcers.
Medicines such as IBUPROFEN 200mg tablets may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

If you experience any of these, or have any other unusual symptoms or concerns, stop taking the tablets and see your doctor.

5. HOW TO STORE

Keep all medicines out of the reach and sight of children.

Do not use after the expiry date shown on the pack.
Do not store above 25°C. Store in the original container.

HOW CAN YOU OBTAIN MORE INFORMATION ABOUT IBUPROFEN 200mg TABLETS

This leaflet gives you the most important patient information about IBUPROFEN 200mg tablets. If you have any questions after you have read it, ask your doctor or pharmacist, who will give you further information.

6. FURTHER INFORMATION

Each tablet contains the active ingredient Ibuprofen 200 mg. They also contain: Sucrose, Sodium Citrate, Talc, Croscarmellose Sodium, Stearic Acid, Titanium Dioxide, Silicon Dioxide, Acacia, Carmellose Sodium, Sodium Laurylsulphate, Macrogol, Black Ink (contains Shellac, Iron Oxide Black E172 and Propylene Glycol).

IBUPROFEN 200mg tablets is available in packs of 6, 8, 12 and 16 tablets.

Licence holder:
Reckitt Benckiser Healthcare (UK) Ltd,
Hull, HU8 7DS,
United Kingdom.
Manufacturer:
Reckitt Benckiser International Ltd,
Nottingham, NG90 2DB.
Product Licence No. PL 00063/0573

SEAMING

Date of revision: April 2008

IBUPROFEN 200MG TABLETS
PL 00063/0573
LABELLING

CARTON
PACK SIZE-12 TABLETS

CONTAINER
BLISTER FOIL