Safeguarding public health

MHRA

Public Assessment Report

IBUPROFEN 200 MG TABLETS
EXTRA STRENGTH IBUPROFEN 400 MG TABLETS

(IBUPROFEN)

PL 17907/0159-61

Medicines and Healthcare products Regulatory Agency

IBUPROFEN TABLETS

(IBUPROFEN) PL 17907/0159-61

UKPAR

TABLE OF CONTENTS

Lay Summary	Page 3
Scientific discussion	Page 4
Steps taken for assessment	Page 12
Steps taken after assessment – summary	Page 13
PL 17907/0159 - Summary of Product Characteristics	Page 14
PL 17907/0160 - Summary of Product Characteristics	Page 20
PL 17907/0161 - Summary of Product Characteristics	Page 26
PL 17907/0159 – Carton Label	Page 32
PL 17907/0159 – Foil Labelling	Page 33
PL 17907/0159 - Product Information Leaflet	Page 34
PL 17907/0160 – Carton Label	Page 35
PL 17907/0160 – Foil Labelling	Page 36
PL 17907/0160 - Product Information Leaflet	Page 37
PL 17907/0161 – Carton Label	Page 38
PL 17907/0161 – Foil Labelling	Page 39
PL 17907/0161 - Product Information Leaflet	Page 40

IBUPROFEN TABLETS

(IBUPROFEN) PL 17907/0159-61

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Bristol Laboratories Limited three Marketing Authorisations (licence) for the medicinal products Ibuprofen Tablets. Two of the licences, PL 17907/0159 and 0160 are to market Ibuprofen 200 mg Tablets (GSL (general sale list) legal status and P (pharmacy) legal status respectively). The third licence, PL 17907/0161, is for Extra Strength Ibuprofen 400 mg Tablets (P legal status).

Ibuprofen 200mg and 400mg Tablets contain the respective amounts of Ibuprofen. Ibuprofen is indicated for the treatment of rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza.

This is an abridged application made under Article 10c [formerly Article 10.1(a)(i)] of EC Directive 2001/83.). The applicant claims essential similarity to:
Ibuprofen 200mg and 400mg tablets BP (white sugar coated tablets with GSL, P and POM legal status), PL 00211/0024 and 0025, granted September 1994, held by The Wallis Laboratory.
These were in turn simple abridged applications of PL 00401/0016 and 0017, held by Steinhard, default conversions granted in March 1994.

Note that CP Pharmaceuticals is acted on behalf of Bristol Laboratories with these applications. The former was bought out by Wockhardt, India in July 2003. Wockhardt already own the cross reference Marketing Authorisation Holder (MAH), The Wallis Laboratory. All regulatory work for Wallis is now undertaken by CP Pharmaceuticals Ltd.

No new or unexpected safety concerns arose from these simple applications and it was therefore judged that the benefits of using Ibuprofen Tablets outweigh the risks; hence Marketing Authorisations have been granted.

IBUPROFEN TABLETS

(IBUPROFEN) PL 17907/0159-61

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction	Page 5
Pharmaceutical assessment	Page 6
Preclinical assessment	Page 9
Clinical assessment	Page 10
Overall conclusions and risk benefit assessment	Page 11

INTRODUCTION

The UK granted marketing authorisations for the medicinal product Ibuprofen 200 mg Tablets and Extra Strength Ibuprofen 400 mg Tablets (PL 17907/0159-61) to Bristol Laboratories on 24th May 2006.

This is an abridged application made under Article 10c [formerly Article 10.1(a)(i)] of EC Directive 2001/83.). The applicant claims essential similarity to:
Ibuprofen 200mg and 400mg tablets BP (white sugar coated tablets with GSL, P and POM legal status), PL 00211/0024 and 0025, granted September 1994, held by The Wallis Laboratory.
These were in turn simple abridged applications of PL 00401/0016 and 0017, held by Steinhard, default conversions granted in March 1994.

No new data were submitted for this simple application, nor were any necessary, as the data are identical to that of the previously granted cross-referenced product.

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

Ibuprofen is indicated for the treatment of rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza.

PHARMACEUTICAL ASSESSMENT

PL Number:	PL 17907 / 0159, 0160 and 0161
Name of Product:	Ibuprofen 200mg Tablets (with GSL legal status) Ibuprofen 200mg Tablets (with P legal status) Extra Strength Ibuprofen 400mg Tablets (with P legal status)
Active:	Ibuprofen Ph Eur.
Company Name:	Bristol Laboratories Limited
E.C. Article:	10.1c (previously 10.1(a)(i)

Legal Basis

These are simple abridged applications for:

1. Ibuprofen 200mg Tablets
   (white sugar coated tablets with GSL legal status), PL 17909/0159.
2. Ibuprofen 200mg Tablets
   (white sugar coated tablets with P legal status), PL 17909/0160.
3. Extra Strength Ibuprofen 400mg Tablets
   (white sugar coated tablets with P legal status), PL 17909/0161.

The applicant claims essential similarity, under article under article 10.1c to:
Ibuprofen 200mg and 400mg tablets BP (white sugar coated tablets with GSL, P and POM legal status); respectively PL 00211/0024 and 0025, granted September 1994, held by The Wallis Laboratory.
These were in turn simple abridged applications of PL 00401/0016 and 0017, held by Steinhard, default conversions granted in March 1994.

It is noted that CP Pharmaceuticals is acting on behalf of Bristol Laboratories with these applications. The former was bought out by Wockhardt, India in July 2003. Wockhardt already own the cross reference MAH, The Wallis Laboratory. All regulatory work for Wallis is now undertaken by CP Pharmaceuticals Ltd.

The legal basis is satisfactory.

Legal Status

The GSL application is in line with the current requirements for Ibuprofen, which are:

- Maximum strength 200mg
- For the treatment of rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza.
- Adults and children over 12.
- Maximum dosage: 400mg, Maximum daily dosage: 1200mg
- Maximum pack size: 16 tabs or caps.

The P applications are in line with the current requirements for Ibuprofen, which are: The product will be prescription only medicine (POM) unless the following conditions are met:

- Rheumatic and muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza.
- Maximum dosage: 400mg, Maximum daily dosage: 1200mg.

Letters of consent

A satisfactory letters of access has been supplied.
The applicant has also provided satisfactory written confirmation that they have appropriate access to all the data supporting the application.
The finished product manufacturer is Wockhardt Limited, in India. Confirmation that the finished product manufacturer is prepared to manufacture the products on the applicant's behalf has been provided

TSE

The MAA form (Section 2.6.2) indicates no ingredients in the product that are TSE susceptible.

Expert reports

The applicant has provided expert reports in Module 1 of the application, written by appropriately qualified experts. Signed declarations and a copy of the experts' CV has also been provided

These reports confirm the application to be identical with the reference product in all particulars.

The report is accepted.

Product name

It is based on the active ingredient and is acceptable.

Summary of Product Characteristics (SPC)

The SPC has been updated in line with regulation (EC) 726/2004 and is in line with the reference product.

Patient Information Leaflet (PIL)

The PIL has been updated in line with current guidelines and is in line with the reference product.

Label

The carton and foil labels has been updated in line with current guidelines and is in line with the reference product.

MAA form

The sites of manufacture, assembly, QC and batch release are in line with the reference product. A satisfactory manufacturing licence is provided.

Section 4 Additional Information

Satisfactory

CONCLUSION

A marketing authorisation may be granted for this product.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications 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 data previously assessed for the cross-referenced product and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

No new or unexpected safety concerns arose from this application.

The SPC and combined PIL-labelling are satisfactory and consistent with those of the cross-referenced 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 comparable to the cross-referenced product. Extensive clinical experience with the active ingredient ibuprofen is considered to have demonstrated the therapeutic value of the compound. The risk-benefit assessment is therefore considered to be favourable.

IBUPROFEN TABLETS

(IBUPROFEN) PL 17907/0159-61

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 26th October 2004.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 14th February 2005.
3	Following assessment of the application the MHRA requested further information on 9th February 2006.
4	The applicant responded to the MHRA's requests, providing further information on 24th March 2006.
5	Following assessment of the responses the MHRA requested further information on 30th March 2006.
6	The applicant responded to the MHRA's requests, providing further information on 12th May 2006.
7	The application was determined on 24th May 2006.

IBUPROFEN TABLETS

(IBUPROFEN) PL 17907/0159-61

STEPS TAKEN AFTER ASSESSMENT

Date Submitted	Application Type	Scope	Outcome

IBUPROFEN 200 MG TABLETS (IBUPROFEN)
PL 17907/0159

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Ibuprofen 200mg Tablets BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Ibuprofen 200mg
For excipients see 6.1

3 PHARMACEUTICAL FORM
Coated tablet
Round white sugar coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza.

4.2 Posology and method of administration

For oral administration and short-term use only.

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

Adults, the elderly and Children over 12 years:
200 – 400mg, up to three times a day as required.

Leave at least four hours between doses and do not take more than 1200mg in any 24 hour period.

Do not give to children under 12 years of age, except on the advice of a doctor.

4.3 Contraindications

Hypersensitivity to ibuprofen or any of the other constituents 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 previous peptic ulcer.

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

Use with concomitant NSAIDs including cyclo-oxygenase-2 specific inhibitors (see section 4.5 Interactions)

Severe hepatic failure, renal failure of heart failure (see section 4.4 Special warnings and precautions for use)

Late trimester of pregnancy (See section 4.5 Pregnancy and Lactation)

4.4 Special warnings and precautions for use

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

Undesirable effects may be minimized by using the minimum effective dose for the shortest possible duration**.**
The elderly are at increased risk of the serious consequences of adverse reactions.

Systemic lupus erythematus and mixed connective tissue disease- increased risk of aseptic meningitis (see Section 4.8 Undesirable effects)

Chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated. (See Section 4.8 Undesirable effects)
Hypertension and/or cardiac impairment as renal function may deteriorate (see section 4.3 Contraindications and section 4.8 Undesirable effects)

Renal impairment as renal function may deteriorate (sees section 4.3 Contraindications and section 4.8 Undesirable effects)

Hepatic dysfunction (sees section 4.3 Contraindications and section 4.8 Undesirable effects)

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.

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 serious GI events.

Patients with a history of GI toxicity, particularly when 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 gastrotoxicity or bleeding, such as cortosteroids, or anticoagulants such as warfarin or anti-platelet agents such as aspirin (see section 4.5 Interactions)

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

Patients with rare heredity problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The label will include:
Read the enclosed leaflet before taking this product.

- Do not take if you have or have ever had a stomach ulcer**,** perforation or bleeding.
- are allergic to ibuprofen or any other ingredient of the product, aspirin, or other related painkillers.
- taking other NSAID pain killers or aspirin with a daily dose above 75mg
- are in the last three months of pregnancy

Speak to a pharmacist or your doctor before taking this product if you

- have asthma liver, heart, kidney or bowel problems
- are in the first six months of pregnancy

If symptoms persist or worsen**,** consult your doctor

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen should not be used 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 4.3 Contraindications)
Other NSAIDs: As these may increase the risk of adverse effects (see section 4.3 Contraindications)

Ibuprofen should be used with caution in combination with:
-Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin (See section 4.4)

Antihypertensives and diuretics: NSAIDs may diminish the effect of these drugs.

Cortosteroids: May increase the risk of adverse reactions in the gastrointestinal tract (see section 4.4 Special Warnings)

Lithium: There is evidence for potential increases in plasma levels of lithium.
Methotrexate: There is potential for an increase in plasma methotrexate.

Zidovudine: There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

4.6 Pregnancy and lactation

Whilst no teratogenic effects have been demonstrated in animal experiments, the use of ibuprofen during pregnancy should, 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 duration increased with an increased bleeding tendency in both mother and child. (See section 4.3 Contraindications).
In limited studies, ibuprofen appears in 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 doses and duration of therapy.

4.8 Undesirable effects

Hypersensitivity reactions have been reported and these may consist of:
(a) non-specific allergic reaction and anaphylaxis
(b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea,
(c) Various skin reactions, *e.g.*, pruritus, urticaria, angioedema and, more rarely exfoliative and, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

The following list of adverse effects relates to those experienced with ibuprofen as OTC doses, 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 urticara and pruritus
Very rare: severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension, (anaphlaxis, angioedema or severe shock).
Exacerbation of asthma and bronchospasm.

Gastrointestinal:
Uncommon: abdominal pain, nausea and dyspepsia.
Rare: diarrhoea, flatulence, constipation and vomiting.

Very rare: peptic ulcer, perforation or gastrointestinal haemorrhage, sometimes fatal, particularly in the elderly. Exacerbation of ulcerative colitis and Crohn's disease. (See section 4.4)

Nervous system:
Uncommon: headache

Renal:
Very rare: acute acute renal failure, papillary necrosis especially in long-term use, associated with increased serum urea 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.

Skin:
Uncommon: Various skin rashes. Very rare: Severe forms of skin reactions such as erythema multiforme and 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)

4.9 Overdose

In children ingestion of more than 400mg/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 one hour of ingestion of a potentially toxic amount. Frequent or prolonged convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly 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.
The half life of ibuprofen is about 2 hours. In limited studies, ibuprofen appears in the breast milk in very low concentrations.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Colloidal anhydrous silica
Potato Starch
Povidone
Microcrystalline cellulose
Alginic acid
Magnesium stearate
Sodium lauryl sulphate
Sodium starch glycollate
Croscarmellose sodium

Coating Materials
PVAP sealcote (contains polyvinyl acetate phthalate & stearic acid)
Purified talc
Sucrose
Calcium carbonate
Acacia
Titanium dioxide (E171)
Carnauba wax

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.
Keep the blister tightly closed and in the outer carton to protect from moisture and light.

6.5 Nature and contents of container

Blister Packs.

Tablets are packed individually in pre-moulded PVC film and sealed with aluminium foil.

Pack sizes: 8, 12, 16 tablets

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Bristol Laboratories Limited
Unit 3, Canalside,
Northbridge Road,
Berkhamsted,
HP4 1EG

8 MARKETING AUTHORISATION NUMBER(S)

PL 17907/0159

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/05/2006

10 DATE OF REVISION OF THE TEXT

23/05/2006

11 DOSIMETRY (IF APPLICABLE)

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

IBUPROFEN 200 MG TABLETS (IBUPROFEN)
PL 17907/0160

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ibuprofen 200mg Tablets BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 200mg
For excipients see 6.1

3 PHARMACEUTICAL FORM

Coated tablet
Round white sugar coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Rheumatic or muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, ~~a~~ feverishness, symptoms of colds and influenza.

4.2 Posology and method of administration

For oral administration and short-term use only.

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

Adults, the elderly and Children over 12 years:
200 – 400mg, up to three times a day as required.

Leave at least four hours between doses and do not take more than 1200mg in any 24 hour period.

Do not give to children under 12 years of age, except on the advice of a doctor.

4.3 Contraindications

Hypersensitivity to ibuprofen or any of the other constituents 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 previous peptic ulcer.

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

Use with concomitant NSAIDs including cyclo-oxygenase-2 specific inhibitors (see section 4.5 Interactions)

Severe hepatic failure, renal failure of heart failure (see section 4.4 Special warnings and precautions for use)

Late trimester of pregnancy (See section 4.5 Pregnancy and Lactation)

4.4 Special warnings and precautions for use

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

Undesirable effects may be minimized by using the minimum effective dose for the shortest possible duration**.**
The elderly are at increased risk of the serious consequences of adverse reactions.

Systemic lupus erythematus and mixed connective tissue disease- increased risk of aseptic meningitis (see Section 4.8 Undesirable effects)

Chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated. (See Section 4.8 Undesirable effects)
Hypertension and/or cardiac impairment as renal function may deteriorate (see section 4.3 Contraindications and section 4.8 Undesirable effects)

Renal impairment as renal function may deteriorate (sees section 4.3 Contraindications and section 4.8 Undesirable effects)

Hepatic dysfunction (sees section 4.3 Contraindications and section 4.8 Undesirable effects)

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.

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 serious GI events.

Patients with a history of GI toxicity, particularly when 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 gastrotoxicity or bleeding, such as cortosteroids, or anticoagulants such as warfarin or anti-platelet agents such as aspirin (see section 4.5 Interactions)

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

Patients with rare heredity problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The label will include:
Read the enclosed leaflet before taking this product.

- Do not take if you have or have ever had a stomach ulcer**,** perforation or bleeding.
- are allergic to ibuprofen or any other ingredient of the product, aspirin, or other related painkillers.
- taking other NSAID pain killers or aspirin with a daily dose above 75mg
- are in the last three months of pregnancy

Speak to a pharmacist or your doctor before taking this product if you

- have asthma liver, heart, kidney or bowel problems
- are in the first six months of pregnancy

If symptoms persist or worsen**,** consult your doctor

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen should not be used 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 4.3 Contraindications)

Other NSAIDs: As these may increase the risk of adverse effects (see section 4.3 Contraindications)

Ibuprofen should be used with caution in combination with:
-Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin (See section 4.4 Special Warnings)

Antihypertensives and diuretics: NSAIDs may diminish the effect of these drugs.

Cortosteroids: May increase the risk of adverse reactions in the gastrointestinal tract (see section 4.4 Special Warnings)

Lithium: There is evidence for potential increases in plasma levels of lithium.
Methotrexate: There is potential for an increase in plasma methotrexate.

Zidovudine: There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

4.6 Pregnancy and lactation

Whilst no teratogenic effects have been demonstrated in animal experiments, the use of ibuprofen during pregnancy should, 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 duration increased with an increased bleeding tendency in both mother and child. (See section 4.3 Contraindications).
In limited studies, ibuprofen appears in 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 doses and duration of therapy.

4.8 Undesirable effects

Hypersensitivity reactions have been reported and these may consist of:
(a) non-specific allergic reaction and anaphylaxis
(b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea,
(c) Various skin reactions, *e.g.*, pruritus, urticaria, angioedema and, more rarely exfoliative and, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

The following list of adverse effects relates to those experienced with ibuprofen as OTC doses, 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 urticara and pruritus
Very rare: severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension, (anaphlaxis, angioedema or severe shock).
Exacerbation of asthma and bronchospasm.

Gastrointestinal:
Uncommon: abdominal pain, nausea and dyspepsia.
Rare: diarrhoea, flatulence, constipation and vomiting.
Very rare: peptic ulcer, perforation or gastrointestinal haemorrhage, sometimes fatal, particularly in the elderly. Exacerbation of ulcerative colitis and Crohn's disease. (See section 4.4)

Nervous system:
Uncommon: headache

Renal:
Very rare: acute acute renal failure, papillary necrosis especially in long-term use, associated with increased serum urea 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.

Skin:
Uncommon: Various skin rashes. Very rare: Severe forms of skin reactions such as erythema multiforme and 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)

4.9 Overdose

In children ingestion of more than 400mg/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 one hour of ingestion of a potentially toxic amount. Frequent or prolonged convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly 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.

The half life of ibuprofen is about 2 hours. In limited studies, ibuprofen appears in the breast milk in very low concentrations.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Colloidal anhydrous silica
Potato Starch
Povidone
Microcrystalline cellulose
Alginic acid
Magnesium stearate
Sodium lauryl sulphate
Sodium starch glycollate
Croscarmellose sodium

Coating Materials
PVAP sealcote (contains polyvinyl acetate phthalate & stearic acid)
Purified talc
Sucrose
Calcium carbonate
Acacia
Titanium dioxide (E171)
Carnauba wax

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.
Keep the blister tightly closed and in the outer carton to protect from moisture and light.

6.5 Nature and contents of container

Blister Packs.

Tablets are packed individually in pre-moulded PVC film and sealed with aluminium foil.

Pack sizes: 24,25,32,48,50,56,64,72,84,96 and 100tablets.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Bristol Laboratories Limited
Unit 3, Canalside,
Northbridge Road,
Berkhamsted,
HP4 1EG

8 MARKETING AUTHORISATION NUMBER(S)

PL 17907/0160

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/05/2006

10 DATE OF REVISION OF THE TEXT

23/05/2006

11 DOSIMETRY (IF APPLICABLE)

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

EXTRA STRENGTH IBUPROFEN 400 MG TABLETS (IBUPROFEN)
PL 17907/0161

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Extra Strength Ibuprofen 400mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Ibuprofen 400mg
For excipients see 6.1

3 PHARMACEUTICAL FORM
Coated tablet
Round white sugar coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Rheumatic or muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, ~~a~~ feverishness, symptoms of colds and influenza.

4.2 Posology and method of administration

For oral administration and short-term use only.

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

Adults, the elderly and Children over 12 years:
200 – 400mg, up to three times a day as required.

Leave at least four hours between doses and do not take more than 1200mg in any 24 hour period.

Do not give to children under 12 years of age, except on the advice of a doctor.

4.3 Contraindications

Hypersensitivity to ibuprofen or any of the other constituents 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 previous peptic ulcer.

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

Use with concomitant NSAIDs including cyclo-oxygenase-2 specific inhibitors (see section 4.5 Interactions)

Severe hepatic failure, renal failure of heart failure (see section 4.4 Special warnings and precautions for use)

Late trimester of pregnancy (See section 4.5 Pregnancy and Lactation)

4.4 Special warnings and precautions for use

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

Undesirable effects may be minimized by using the minimum effective dose for the shortest possible duration**.**
The elderly are at increased risk of the serious consequences of adverse reactions.

Systemic lupus erythematus and mixed connective tissue disease- increased risk of aseptic meningitis (see Section 4.8 Undesirable effects)

Chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated. (See Section 4.8 Undesirable effects)
Hypertension and/or cardiac impairment as renal function may deteriorate (see section 4.3 Contraindications and section 4.8 Undesirable effects)

Renal impairment as renal function may deteriorate (sees section 4.3 Contraindications and section 4.8 Undesirable effects)

Hepatic dysfunction (sees section 4.3 Contraindications and section 4.8 Undesirable effects)

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.

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 serious GI events.

Patients with a history of GI toxicity, particularly when 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 gastrotoxicity or bleeding, such as cortosteroids, or anticoagulants such as warfarin or anti-platelet agents such as aspirin (see section 4.5 Interactions)

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

Patients with rare heredity problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The label will include:

Read the enclosed leaflet before taking this product.

- Do not take if you have or have ever had a stomach ulcer**,** perforation or bleeding.
- are allergic to ibuprofen or any other ingredient of the product, aspirin, or other related painkillers.
- taking other NSAID pain killers or aspirin with a daily dose above 75mg
- are in the last three months of pregnancy

Speak to a pharmacist or your doctor before taking this product if you

- have asthma liver, heart, kidney or bowel problems
- are in the first six months of pregnancy
- If symptoms persist or worsen**,** consult your doctor

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen should not be used 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 4.3 Contraindications)
Other NSAIDs: As these may increase the risk of adverse effects (see section 4.3 Contraindications)

Ibuprofen should be used with caution in combination with:
Anticoagulants: NSAIDs may enhance the effects of anticoagulants, such as warfarin (See section 4.4)

Antihypertensives and diuretics: NSAIDs may diminish the effect of these drugs.

Cortosteroids: May increase the risk of adverse reactions in the gastrointestinal tract (see section 4.4 Special Warnings)

Lithium: There is evidence for potential increases in plasma levels of lithium.
Methotrexate: There is potential for an increase in plasma methotrexate.

Zidovudine: There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

4.6 Pregnancy and lactation

Whilst no teratogenic effects have been demonstrated in animal experiments, the use of ibuprofen during pregnancy should, 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 duration increased with an increased bleeding tendency in both mother and child. (See section 4.3 Contraindications).
In limited studies, ibuprofen appears in 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 doses and duration of therapy.

4.8 Undesirable effects

Hypersensitivity reactions have been reported and these may consist of:
(a) non-specific allergic reaction and anaphylaxis
(b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea,
(c) Various skin reactions, *e.g.*, pruritus, urticaria, angioedema and, more rarely exfoliative and, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

The following list of adverse effects relates to those experienced with ibuprofen as OTC doses, 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 urticara and pruritus
Very rare: severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension, (anaphlaxis, angioedema or severe shock).
Exacerbation of asthma and bronchospasm.

Gastrointestinal:
Uncommon: abdominal pain, nausea and dyspepsia.
Rare: diarrhoea, flatulence, constipation and vomiting.

Very rare: peptic ulcer, perforation or gastrointestinal haemorrhage, sometimes fatal, particularly in the elderly. Exacerbation of ulcerative colitis and Crohn's disease. (See section 4.4)

Nervous system:
Uncommon: headache

Renal:
Very rare: acute acute renal failure, papillary necrosis especially in long-term use, associated with increased serum urea 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.

Skin:
Uncommon: Various skin rashes. Very rare: Severe forms of skin reactions such as erythema multiforme and 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)

4.9 Overdose

In children ingestion of more than 400mg/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 one hour of ingestion of a potentially toxic amount. Frequent or prolonged convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly 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.
The half life of ibuprofen is about 2 hours. In limited studies, ibuprofen appears in the breast milk in very low concentrations.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Colloidal anhydrous silica
Potato Starch
Povidone
Microcrystalline cellulose
Alginic acid
Magnesium stearate
Sodium lauryl sulphate
Sodium starch glycollate
Croscarmellose sodium

Coating Materials
PVAP sealcote (contains polyvinyl acetate phthalate & stearic acid)
Purified talc
Sucrose
Calcium carbonate
Acacia
Titanium dioxide (E171)
Carnauba wax

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.
Keep the blister tightly closed and in the outer carton to protect from moisture and light.

6.5 Nature and contents of container

Blister Packs.

Tablets are packed individually in pre-moulded PVC film and sealed with aluminium foil.

Pack sizes: 8, 12, 16, 24, 32, 48, 56, 64, 72, 84, 96.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Bristol Laboratories Limited
Unit 3, Canalside,
Northbridge Road,
Berkhamsted,
HP4 1EG

8 MARKETING AUTHORISATION NUMBER(S)

PL 17907/0161

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/05/2006

10 DATE OF REVISION OF THE TEXT

23/05/2006

11 DOSIMETRY (IF APPLICABLE)

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

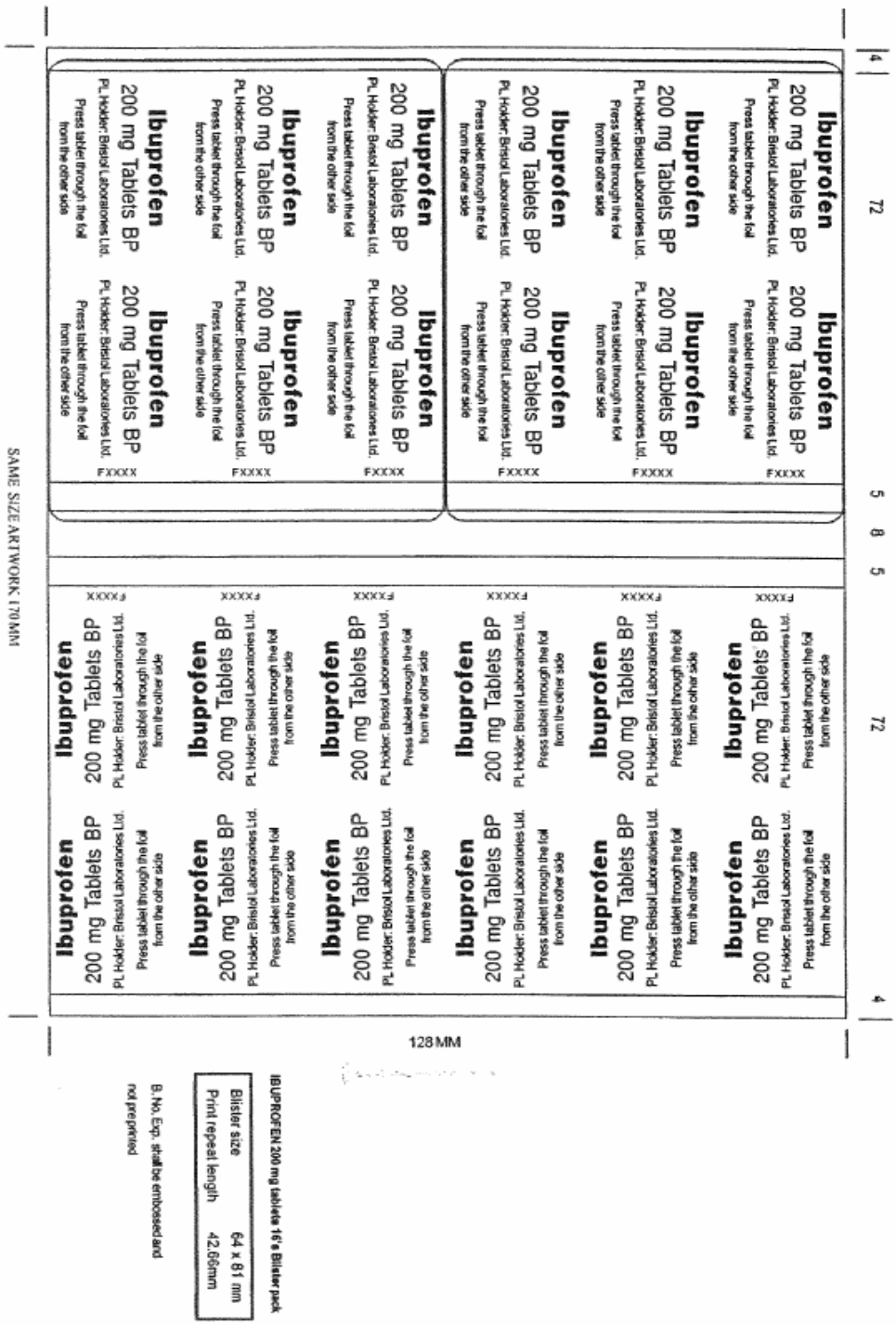
IBUPROFEN 200MG TABLETS (IBUPROFEN)
PL 17907/0159
CARTON LABEL

Same Size Artwork
Size: 86 x 17 x 70 mm
Graphic Creations

Pantone 526

Pantone 1925

FOIL LABEL



IBUPROFEN 200 mg tablets 16's Blister pack

Blister size	64 x 81 mm
Print repeat length	42.66mm

B. No. Exp. shall be embossed and not preprinted

PAITENT INFORMATION LEAFLET

PACKAGE LEAFLET

Ibuprofen 200mg Tablets BP

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription, for you to treat mild illness without a doctor's help. Nevertheless you still need to use Ibuprofen 200mg Tablets BP carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

In this leaflet:
1. What Ibuprofen 200mg Tablets BP is and what it is used for
2. Before you take Ibuprofen 200mg Tablets BP
3. How to take Ibuprofen 200mg Tablets BP
4. Possible side effects
5. Storing Ibuprofen 200mg Tablets BP

- The active substance is ibuprofen
- The other ingredients are sucrose, microcrystalline cellulose, potato starch, sodium starch glycollate, povidone, alginic acid, colloidal anhydrous silica, talc, magnesium stearate, PVAP sealcote (polyvinyl acetate phthalate & stearic acid), croscarmellose sodium, sodium lauryl sulphate, titanium dioxide (E171), calcium carbonate, acacia and carnauba wax.

MA Holder: Bristol Laboratories, Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG

Manufactured By: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Pack size: 8, 12 and 16 tablets

WHAT IBUPROFEN 200MG TABLETS BP IS AND WHAT IT IS USED FOR

Ibuprofen 200mg Tablets BP are white, round sugar-coated tablets. Ibuprofen belongs to a class of medicines called the Non Steroidal Anti-Inflammatory Drugs and it has pain relieving, temperature reducing and anti-inflammatory properties.

Ibuprofen 200mg tablets BP are used to treat rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, period pain, feverishness, symptoms of colds and influenza.

BEFORE YOU TAKE IBUPROFEN 200MG TABLETS BP

Do not take Ibuprofen 200mg Tablets BP:
- if you are hypersensitive (allergic) to ibuprofen or any of the other ingredients
- if you have had a worsening of asthma, allergic rash or an itchy, runny nose when taking ibuprofen, aspirin or other similar medicines
- are in the last three months of pregnancy
- have a history of stomach ulcer, perforation or bleeding
- are taking any other NSAID pain killer or aspirin with a daily dose above 75mg

Take special care with Ibuprofen 200mg Tablets BP:
- if you have been told by your doctor that you have an intolerance to some sugars
- if you suffer from asthma or allergic disease
- if you are elderly
- suffer from liver, kidney, heart or bowel problems
- are in the first six months of pregnancy

Fertility
Ibuprofen belongs to a group of medicines, which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that ibuprofen, used occasionally, will affect your chances of becoming pregnant, however tell your doctor before taking this medicine if you have problems becoming pregnant.

Breast-feeding
Ask you doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Ibuprofen should not affect your ability to drive or use machines at the recommended dose. If you are affected, do not drive or operate machinery.

SAME SIZE ARTWORK
143 x 210 mm
Graphic Creations

Important information about some of the ingredients of Ibuprofen 200mg Tablets BP:
This product contains sucrose – if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines:
Ibuprofen should not be taken with
- Aspirin at doses of above 75mg daily. if you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take ibuprofen.
- Other NSAID pain killers

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed,
- Anticoagulants such as warfarin
- Medicines for high blood pressure (antihypertensives) or water tablets (diuretics)
- Corticosteroids
- Lithium
- Methotrexate
- Zidovudine used to treat virus infection or HIV,

HOW TO TAKE IBUPROFEN 200MG TABLETS BP

For oral administration only.
Dose
Adults and children over 12 years: 1 to 2 tablets up to three times a day. Leave at least four hours between doses. Do not take any more than 6 tablets in any 24 hour period.
DO NOT GIVE TO CHILDREN UNDER 12 YEARS OF AGE, EXCEPT ON THE ADVICE OF A DOCTOR.

If you miss a single dose of Ibuprofen Tablets BP 200mg, do not worry and take the next one at the normal time. **DO NOT DOUBLE UP ON A DOSE TO MAKE UP FOR THE MISSING ONE.**

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 ibuprofen for longer than 10 days. If symptoms persist or worsen consult your doctor, who may instruct you to continue taking the medicine.

If you accidentally take a large number of tablets (overdose), you should contact the nearest hospital casualty department or tell your doctor immediately.

POSSIBLE SIDE EFFECTS

Like all medicines, Ibuprofen 200mg Tablets BP can have side effects.

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:
Pass blood in your faeces (stools/motions)
Pass black tarry stools
Vomit any blood or dark particles that look like coffee grounds.

STOP TAKING the medicine and tell your doctor if you experience:
Indigestion or heartburn
Abdominal pain (pains in your stomach) or other abnormal stomach symptoms
Unexplained wheezing, shortness of breath, skin rash, itching, bruising or facial swelling.
Other side effects may include headache, renal and liver problems, flu-like symptoms and exhaustion.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING IBUPROFEN 200MG TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C.
Keep the blister tightly closed and in the outer carton to protect from moisture and light.

Do not use after the expiry date stated on the carton
Do not use Ibuprofen 200mg Tablets BP if you notice visible sign of deterioration such as discolouration.

This leaflet was last approved on May 2006

Further information
For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.
Bristol Laboratories Limited., Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG

SAME SIZE ARTWORK
143 x 210 mm
Graphic Creations

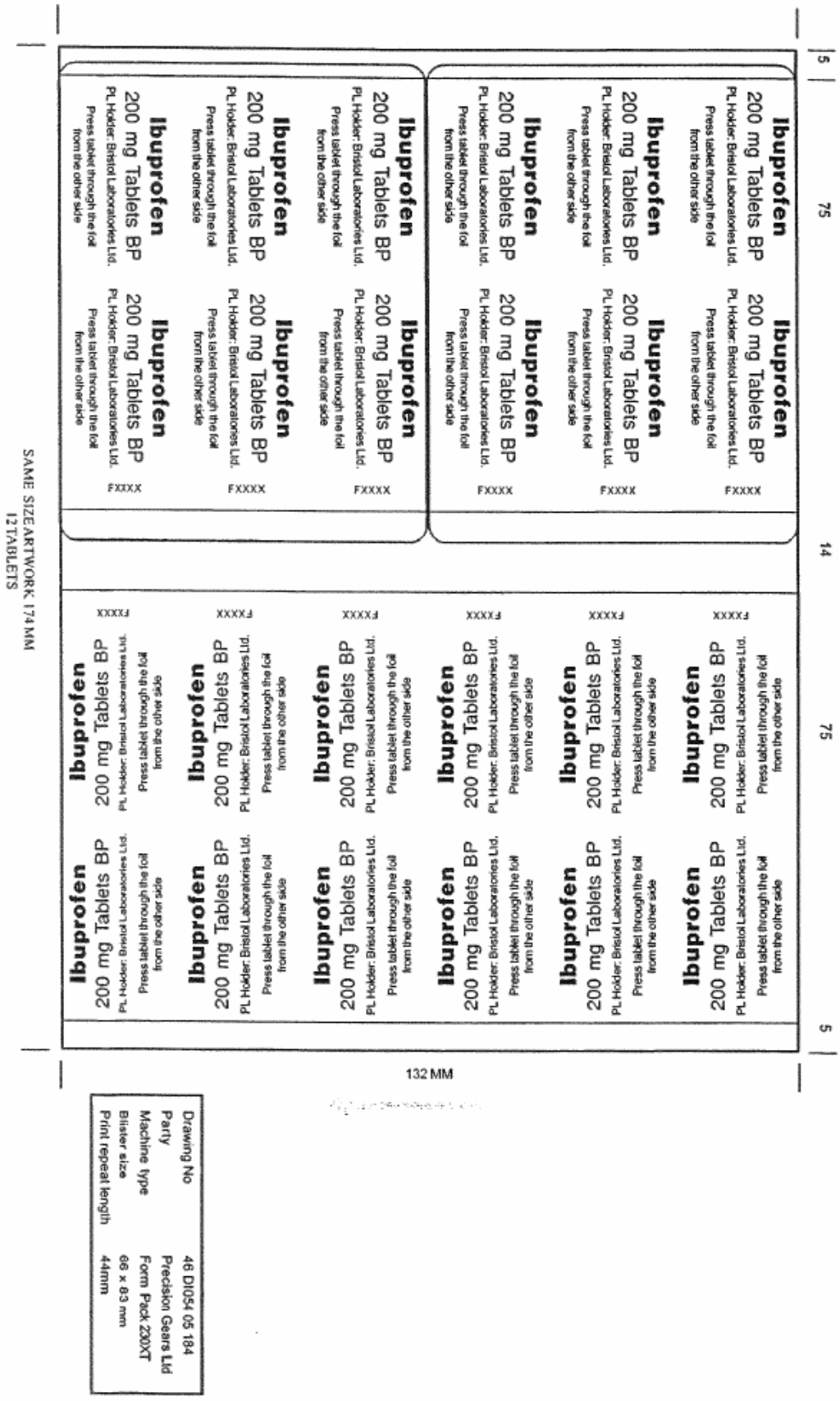
IBUPROFEN 200MG TABLETS (IBUPROFEN)
PL 17907/0160
<u>CARTON LABEL</u>

Artwork same size
size: 86x35x70mm
Graphic Creations

Pantone 357

Pantone 1925

FOIL LABEL



Drawing No	46 DI054 05 184
Party	Precision Gears Ltd
Machine type	Form Pack 230XT
Blister size	66 x 83 mm
Print repeat length	44mm

PAITENT INFORMATION LEAFLET

PACKAGE LEAFLET

Ibuprofen 200mg Tablets BP

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription, for you to treat mild illness without a doctor's help. Nevertheless you still need to use Ibuprofen 200mg Tablets BP carefully to get the best results from it.
- Keep this leaflet, You may need to read it again,
- Ask your pharmacist if you need more information or advice,
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

In this leaflet:
1. What Ibuprofen 200mg Tablets BP is and what it is used for
2. Before you take Ibuprofen 200mg Tablets BP
3. How to take Ibuprofen 200mg Tablets BP
4. Possible side effects
5. Storing Ibuprofen 200mg Tablets BP

- The active substance is ibuprofen
- The other ingredients are sucrose, microcrystalline cellulose, potato starch, sodium starch glycollate, povidone, alginic acid, colloidal anhydrous silica, talc, magnesium stearate, PVAP sealcote (polyvinyl acetate phthalate & stearic acid), croscarmellose sodium, sodium lauryl sulphate, titanium dioxide (E171), calcium carbonate, acacia and carnauba wax.

MA Holder: Bristol Laboratories, Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG

Manufactured By: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Pack size: 24, 25, 32, 48, 50, 56, 64, 72, 84, 96 and 100 tablets

WHAT IBUPROFEN 200MG TABLETS BP IS AND WHAT IT IS USED FOR

Ibuprofen 200mg Tablets BP are white, round sugar-coated tablets, Ibuprofen belongs to a class of medicines called the Non Steroidal Anti-Inflammatory Drugs and it has pain relieving, temperature reducing and anti-inflammatory properties.

Ibuprofen 200mg tablets BP are used to treat rheumatic or muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, period pain, feverishness, symptoms of colds and influenza.

BEFORE YOU TAKE IBUPROFEN 200MG TABLETS BP

Do not take Ibuprofen 200mg Tablets BP:
- if you are hypersensitive (allergic) to ibuprofen or any of the other ingredients
- if you have had a worsening of asthma, allergic rash or an itchy, runny nose when taking ibuprofen, aspirin or other similar medicines
- are in the last three months of pregnancy
- have a history of stomach ulcer, perforation or bleeding
- are taking any other NSAID pain killer or aspirin with a daily dose above 75mg

Take special care with Ibuprofen 200mg Tablets BP:
- if you have been told by your doctor that you have an intolerance to some sugars
- if you suffer from asthma or allergic disease
- if you are elderly
- suffer from liver, kidney, heart or bowel problems
- are in the first six months of pregnancy

Fertility
Ibuprofen belongs to a group of medicines, which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that ibuprofen, used occasionally, will affect your chances of becoming pregnant, however tell your doctor before taking this medicine if you have problems becoming pregnant.

Breast-feeding
Ask you doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Ibuprofen should not affect your ability to drive or use machines at the recommended dose. If you are affected, do not drive or operate machinery.

SAME SIZE ARTWORK
143 x 210 mm
Graphic Creations

Important information about some of the ingredients of Ibuprofen 200mg Tablets BP:
This product contains sucrose – if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines:
Ibuprofen should not be taken with
- Aspirin at doses of above 75mg daily. if you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take ibuprofen,
- Other NSAID pain killers

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed,
- Anticoagulants such as warfarin
- Medicines for high blood pressure (antihypertensives) or water tablets (diuretics)
- Corticosteroids
- Lithium
- Methotrexate
- Zidovudine used to treat virus infection or HIV.

HOW TO TAKE IBUPROFEN 200MG TABLETS BP

For oral administration only.
Dose
Adults and children over 12 years: 1 to 2 tablets up to three times a day. Leave at least four hours between doses. Do not take any more than 6 tablets in any 24 hour period.
DO NOT GIVE TO CHILDREN UNDER 12 YEARS OF AGE, EXCEPT ON THE ADVICE OF A DOCTOR.

If you miss a single dose of Ibuprofen Tablets BP 200mg, do not worry and take the next one at the normal time. **DO NOT DOUBLE UP ON A DOSE TO MAKE UP FOR THE MISSING ONE.**

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 ibuprofen for longer than 10 days. If symptoms persist or worsen consult your doctor, who may instruct you to continue taking the medicine.

If you accidentally take a large number of tablets (overdose), you should contact the nearest hospital casualty department or tell your doctor immediately.

POSSIBLE SIDE EFFECTS

Like all medicines, Ibuprofen 200mg Tablets BP can have side effects.

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:
Pass blood in your faeces (stools/motions)
Pass black tarry stools
Vomit any blood or dark particles that look like coffee grounds.

STOP TAKING the medicine and tell your doctor if you experience:
Indigestion or heartburn
Abdominal pain (pains in your stomach) or other abnormal stomach symptoms
Unexplained wheezing, shortness of breath, skin rash, itching, bruising or facial swelling.
Other side effects may include headache, renal and liver problems, flu-like symptoms and exhaustion.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING IBUPROFEN 200MG TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C,
Keep the blister tightly closed and in the outer carton to protect from moisture and light.

Do not use after the expiry date stated on the carton
Do not use Ibuprofen 200mg Tablets BP if you notice visible sign of deterioration such as discolouration.

This leaflet was last approved on May 2006

Further information
For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.
Bristol Laboratories Limited,, Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG

SAME SIZE ARTWORK
143 x 210 mm
Graphic Creations

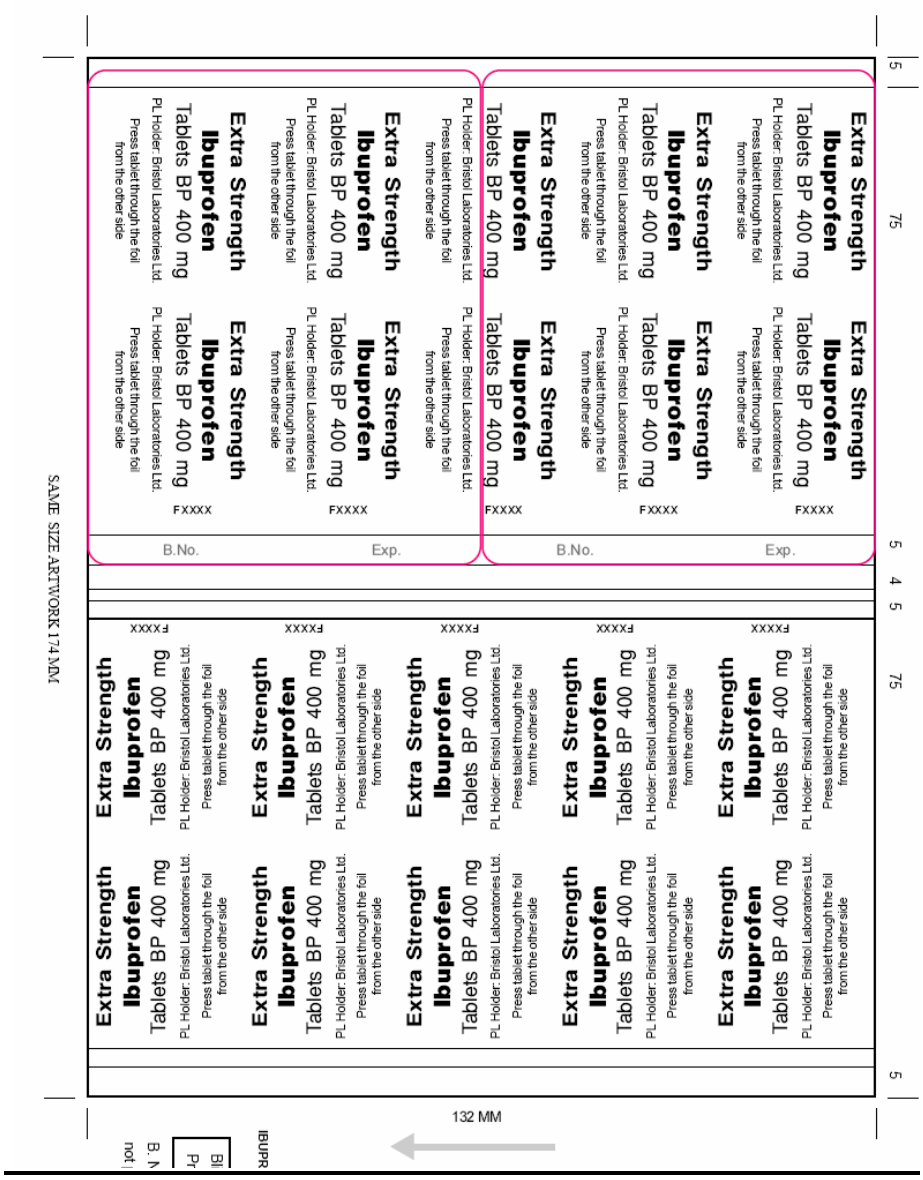
IBUPROFEN 400MG TABLETS (IBUPROFEN)
PL 17907/0161
CARTON LABEL

Same Size Artwork
86 x 23 x 70 mm
Graphic Creations

Pantone reflex blue

Pantone Hexachrome magenta

FOIL LABEL


Extra Strength
Ibuprofen
Tablets BP 400 mg
PL Holder: Bristol Laboratories Ltd.
Press tablet through the foil from the other side
B.No.
Exp.
FXXXX
132 MM
SAME SIZE ARTWORK 174 MM

PAITENT INFORMATION LEAFLET

PACKAGE LEAFLET

Extra Strength
Ibuprofen 400mg Tablets

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription, for you to treat mild illness without a doctor's help. Nevertheless you still need to use Ibuprofen 400mg Tablets carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

In this leaflet:
1. What Ibuprofen 400mg Tablets is and what it is used for
2. Before you take Ibuprofen 400mg Tablets
3. How to take Ibuprofen 400mg Tablets
4. Possible side effects
5. Storing Ibuprofen 400mg Tablets

- The active substance is ibuprofen
- The other ingredients are sucrose, microcrystalline cellulose, potato starch, sodium starch glycollate, povidone, alginic acid, colloidal anhydrous silica, talc, magnesium stearate, PVAP sealcote (polyvinyl acetate phthalate & stearic acid), croscarmellose sodium, sodium lauryl sulphate, titanium dioxide (E171), calcium carbonate, acacia and carnauba wax.

MA Holder: Bristol Laboratories, Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG

Manufactured By: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Pack sizes: 8, 12, 16, 24, 32, 48, 56, 64, 72, 84, 96 *tablets*

WHAT IBUPROFEN 400MG TABLETS ARE AND WHAT THEY ARE USED FOR

Ibuprofen 400mg Tablets are white, round sugar-coated tablets. Ibuprofen belongs to a class of medicines called the Non Steroidal Anti-Inflammatory Drugs and it has pain relieving, temperature reducing and anti-inflammatory properties.

Ibuprofen 400mg Tablets are used to relieve rheumatic or muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine,headache, dental pain, period pain, feverishness, symptoms of colds and influenza.

BEFORE YOU TAKE IBUPROFEN 400MG TABLETS

Do not take Ibuprofen 400mg Tablets:
- if you are hypersensitive (allergic) to ibuprofen or any of the other ingredients
- if you have had a worsening of asthma, allergic rash or an itchy, runny nose when taking ibuprofen, aspirin or other similar medicines
- are in the last three months of pregnancy
- have a history of stomach ulcer, perforation or bleeding
- are taking any other NSAID pain killer or aspirin with a daily dose above 75mg

Take special care with Ibuprofen 400mg Tablets:
- if you have been told by your doctor that you have an intolerance to some sugars
- if you suffer from asthma or allergic disease
- if you are elderly
- suffer from liver, kidney, heart or bowel problems
- are in the last six months of pregnancy

Fertility
Ibuprofen belongs to a group of medicines, which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that ibuprofen, used occasionally, will affect your chances of becoming pregnant, however tell your doctor before taking this medicine if you have problems becoming pregnant.

Breast-feeding
Ask you doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Ibuprofen should not affect your ability to drive or use machines at the recommended dose. If you are affected, do not drive or operate machinery.

Important information about some of the ingredients of Ibuprofen 400mg Tablets.
This product contains sucrose – if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines:
Ibuprofen should not be taken with
- Aspirin at doses of above 75mg daily. if you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take ibuprofen.
- Other NSAID pain killers

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed,
- Anticoagulants such as warfarin
- Medicines for high blood pressure (antihypertensives) or water tablets (diuretics)
- Corticosteroids
- Lithium
- Methotrexate
- Zidovudine used to treat virus infection or HIV.

HOW TO TAKE IBUPROFEN 400MG TABLETS

For oral administration only.
Dose
Adults and children over 12 years: 1 tablet up to three times a day. Leave at least four hours between doses. Do not take any more than 3 tablets in any 24 hour period.
DO NOT GIVE TO CHILDREN UNDER 12 YEARS OF AGE, EXCEPT ON THE ADVICE OF A DOCTOR.

If you miss a single dose of Ibuprofen 400mg Tablets, do not worry and take the next one at the normal time. **DO NOT DOUBLE UP ON A DOSE TO MAKE UP FOR THE MISSING ONE.**

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 ibuprofen for longer than 10 days. If symptoms persist or worsen consult your doctor, who may instruct you to continue taking the medicine.

If you accidentally take a large number of tablets (overdose), you should contact the nearest hospital casualty department or tell your doctor immediately.

POSSIBLE SIDE EFFECTS

Like all medicines, Ibuprofen 400mg Tablets can have side effects.

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:
Pass blood in your faeces (stools/motions)
Pass black tarry stools
Vomit any blood or dark particles that look like coffee grounds.

STOP TAKING the medicine and tell your doctor if you experience:
Indigestion or heartburn
Abdominal pain (pains in your stomach) or other abnormal stomach symptoms
Unexplained wheezing, shortness of breath, skin rash, itching, bruising or facial swelling.
Other side effects may include headache, renal and liver problems, flu-like symptoms and exhaustion.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING IBUPROFEN 400MG TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C.
Keep the blister tightly closed and in the outer carton to protect from moisture and light.
Do not use after the expiry date stated on the carton.
Do not use Ibuprofen 400mg Tablets if you notice visible sign of deterioration such as discolouration.

This leaflet was last approved on May 2006

Further information
For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.
Bristol Laboratories Limited., Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG