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DIMENSIONS 155 x 410 mm

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Project:MOS0140 OTC  
Ibuprofen 200mg

Item(s):LEAFLET

Category:OTC

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N/A

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Pharma

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This scale measures 100mm when artwork is 100%

0

10

20

30

40

50

60

70

80

90

100

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Modifications:

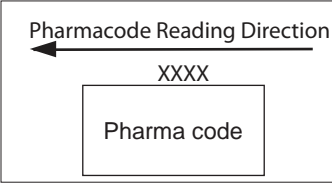
Draft 1: SAFETY UPDATE - NEW FULL TEXT RECEIVED. Draft 2: Uplift in revision date.

Ibuprofen 200mg Tablets (FPL)

P & GSL

Leaflet Size : 155 x 410 mm

MPLL0003\_V01



155 mm

410 mm

ALMUS

Package leaflet: Information for the user  
**IBUPROFEN 200mg TABLETS**  
Ibuprofen

**Please read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days for children and adolescents between 12 and 18 years and after 10 days for adults.

**WHAT IS IN THIS LEAFLET:**

- What Ibuprofen Tablets are and what they are used for
- What you need to know before you take Ibuprofen Tablets
- How to take Ibuprofen Tablets
- Possible side effects
- How to store Ibuprofen Tablets
- Contents of the pack and other information

**1. WHAT IBUPROFEN TABLETS ARE AND WHAT THEY ARE USED FOR**

The active ingredient (which makes the medicine work) is Ibuprofen. It 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 Tablets are used for the relief of:

- Headaches and migraine pain**
- Dental pain and neuralgia**
- Period pain**
- Rheumatic, muscular and back pain**
- Feverishness and symptoms of cold and flu**
- The pain of non-serious arthritis [for Pharmacy (P) only]**

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IBUPROFEN TABLETS**

**Do not take these tablets if you:**

- are allergic to ibuprofen or any of the other ingredients (see section 6) or to aspirin or other painkillers
- have ever had a stomach ulcer, perforation or bleeding
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines
- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-steroidal anti-inflammatory drugs)
- are taking other NSAIDs (Non-steroidal Anti-inflammatory Drugs)
- are taking more than 75mg of aspirin a day. If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take this medicine
- have severe liver or kidney problems
- have heart problems, high blood pressure or blood coagulation disorder
- have breathing difficulties
- are in the last 3 months of pregnancy
- are under 12 years old.

**Warnings and precautions**  
**Talk to your doctor, pharmacist or nurse before taking this product if you:**

- have or have had asthma
- have kidney, heart, liver or bowel problems
- have high cholesterol or previously have had a heart attack or stroke
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- have Systemic Lupus Erythematosus (a condition of the immune system rousing joint pain skin changes and other organ disorders)
- are a smoker
- are in the first 6 months of pregnancy
- have an infection – please see heading “Infections” below.
- are taking ibuprofen for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately Ibuprofen 200 mg Tablets and contact immediately your doctor or medical emergencies if you notice any of these signs.

**Take special care with Ibuprofen 200 mg Tablets: Skin reactions:**

Serious skin reactions have been reported in association with Ibuprofen treatment. You should stop taking Ibuprofen and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic

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Pharmacode Reading Direction

155 mm

410 mm

without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

**Adults, the elderly and children & adolescents between 12 and 18 years:**

Take 1 or 2 tablets with water, up to three times a day as required.

Leave at least four hours between doses.

Do not take more than 6 tablets in 24 hours.

**Do not give to children under 12 years.**

**In children and adolescents between 12 and 18 years:**

If in children and adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

**In adults:**

**Do not take for longer than 10 days** unless your doctor tells you to.

If symptoms persist or the pain or fever worsen, or if any new Symptoms occur, consult your doctor or pharmacist.

**If you take more Ibuprofen Tablets than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.**

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

**If you forget to take Ibuprofen Tablets**

Simply refer to the directions above on how to take the medicine and do not take more than is advised.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Ibuprofen can cause side effects, although not everybody gets them. Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. You may suffer one of the known side effects of NSAIDs (see below). If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

**STOP TAKING the medicine and Seek immediate medical help if you develop:**

reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].

Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).

A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

**Signs of intestinal bleeding** such as: bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds.

**Signs or serious allergic reaction such as:**

- difficulties in breathing or unexplained wheezing
- dizziness or faster heartbeat
- severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g.: Steven-Johnson syndrome)
- swelling of your face, tongue or throat

**Signs of kidney problems such as:**

- passing less or more urine.
- cloudy urine or blood in urine.
- pain in the back and/or swelling (particularly in the legs).

Ibuprofen, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

**Signs of aseptic meningitis** with neck stiffness, headache, feeling sick, being sick, fever or loss of consciousness. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.

**A severe skin reaction known as DRESS syndrome** can occur.

Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

**STOP TAKING the medicine and tell your doctor if you experience following uncommon side effects which may affect up to 1 in 100 people:**

- indigestion, heartburn or feeling sick
- pains in your stomach (abdomen) or other abnormal stomach problems

Pharma code

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Pharmacode Reading Direction

Pharmacode Reading Direction

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Pharma code

MPLL0003\_V01

Leaflet Code : MPLL0003_V01				Customer / Livery : FPL_UK (Almus)	
Colour Scheme : Black				Ref. Artwork : New development	
Prepared By		Reviewed & Checked By		Approved by	
Artwork	Pkg. Development	Marketing	Regulatory	CQA	
Sign.	Sign.	Sign.	Sign.	Sign.	Sign.
Date :	Date :	Date :	Date :	Date :	Date :