Reads This Way

R8000000

NUROFEN®

200mg Tablets and
Nurofen 200mg Caplets

Contains Ibuprofen

INFORMATION FOR THE USER

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to use Nurofen 200mg Tablets and Nurofen 200mg Caplets carefully to get the best results from them.
Keep this leaflet. You may want to read it again.
If you have any further questions after you have read it, ask your doctor or pharmacist.
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.
If any side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.
In this leaflet:

1. What Nurofen 200mg Tablets and Nurofen 200mg Caplets are and what they are used for
2. Before you take Nurofen 200mg Tablets and Nurofen 200mg Caplets
3. How to take Nurofen 200mg Tablets and Nurofen 200mg Caplets
4. Possible side effects
5. How to store Nurofen 200mg Tablets and Nurofen 200mg Caplets
6. Further Information

1. What Nurofen 200mg Tablets and Nurofen 200mg Caplets 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.
Nurofen 200mg Tablets and Nurofen 200mg Caplets 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.**

2. Before taking Nurofen 200mg Tablets and Nurofen 200mg Caplets

Do not take Nurofen 200mg Tablets or Nurofen 200mg Caplets 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.

Check with your pharmacist or your doctor 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 causing joint pain skin changes and other organ disorders)
- are a smoker
- are in the first 6 months of pregnancy.

Taking other medicines
To reduce the risk of side effects, do not take this product with other NSAID containing products (e.g. aspirin, ibuprofen…). If you are on low-dose aspirin (up to 75mg daily), speak to your doctor or pharmacist before you take this medicine.
Nurofen may affect or be affected by some other medicines.
For example:
Avoid taking this product with corticosteroid tablets, quinolone antibiotics or drugs that are prescribed:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- to stimulate your heart (e.g. glycosides),
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- to help you passing water (diuretics),
- for the temporary suppression of your immune system (e.g. methotrexate, ciclosporine, tacrolimus)
- for mania or depression (e.g. Lithium or SSRIs)
- for pregancy termination (e.g. mifepristone)
- for HIV treatment (e.g. zidovudine).

Some other medicines may also affect or be affected by the treatment of Nurofen. You should therefore always seek the advice of your doctor or pharmacist before you use Nurofen with other medicines.
Other warnings

- Nurofen 200mg Tablets and Nurofen 200mg Caplets belongs to a group of medicines which may **impair fertility in women.** This is reversible on stopping the medicine. It is unlikely that Nurofen 200mg Tablets and Nurofen 200mg Caplets, used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Anti-inflammatory/pain-killer medicines such as ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.
- You should discuss your treatment with your doctor or pharmacist before taking Nurofen if you:
  - have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
  - have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- There is a risk of renal impairment in dehydrated children and adolescents.

Pregnancy and breast feeding
Tell your doctor if you become pregnant whilst taking Nurofen.
Do not take this medicine in the last 3 months of pregnancy. Avoid the use of this medicine in the first 6 months of pregnancy, unless the doctor advises otherwise.
Speak to your doctor or pharmacist before taking this medicine if you are breastfeeding.
Important information about some of the ingredients
The quantity of sodium contained in 2 tablets is approximately 1.1mmol, ie about 25.3 mg. This quantity is to be taken into consideration by patients on a controlled sodium diet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Nurofen 200mg Tablets and Nurofen 200mg Caplets

This product is for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms.
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 Nurofen 200mg Tablets and Nurofen 200mg Caplets than you should, you may feel drowsy or nauseous. You should seek immediate medical advice in the event of an overdose, even if you feel well.
If you forget to take Nurofen 200mg Tablets and Nurofen 200mg Caplets.
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, Nurofen 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.

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

- **signs of intestinal bleeding** such as: bright red faeces (stools/motions), black farry stools, vomiting blood or dark particles that look like coffee grounds.
- **signs of 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)
- **signs of aseptic meningitis** with neck stiffness, headache, feeling sick, being sick, fever or consciousness. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.

STOP TAKING the medicine and tell your doctor if you experience the following uncommon side effects which affect 1 to 10 users in 1,000:

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

TELL YOUR DOCTOR if you have any of the following side effects, they become worse or you notice any effects not listed:
Uncommon side effects which affect 1 to 10 users in 1,000:

- allergic reactions, such as skin rashes (urticaria), itching, peeling
- headaches

Rare side effects which affect 1 to 10 users in 10,000:

- flatulence (wind), diarrhoea, constipation and vomiting

Very rare side effects which affect less than 1 user in 10,000:

- blood disorder resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion
- drop in blood pressure or irregular heart beat
- stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis)
- liver problems

Side effects for which the frequency can not be estimated from available data:

- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- worsening of colitis and Crohn's disease

Medicines such as Nurofen 200mg Tablets and Nurofen 200mg Caplets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. See Section 2 'Other warnings'.
Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Nurofen 200mg Tablets and Nurofen 200mg Caplets

Keep all medicines out of the sight and reach of children.
Do not use after the expiry date stated on the carton after EXP.
The expiry date refers to the last day of that month.
Do not store above 25°C. Store in the original pack.

6. Further information

Each tablet or caplet contains the active ingredient Ibuprofen 200mg. They also contain: Sucrose, Sodium Citrate, Talc, Croscarmellose Sodium, Stearic Acid, Titanium Dioxide, Silicon Dioxide, Acacia, Carmellose Sodium, Sodium Laurilsulphate, Macrogol and Black Ink (contains Shellac, Iron Oxide Black (E172) and Propylene Glycol).
Nurofen 200mg Tablets are available in packs of 4, 6, 8, 12, 16, 24, 48 and 96 tablets.
Nurofen 200mg Caplets (capsule shaped tablets) are available in packs 4, 12, 16, 24.
Not all pack size are marketed.

Licence Holder: Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 4AQ.
Manufacturer: Reckitt Benckiser Healthcare International Ltd, NG90 2DB.
Product licence number
Nurofen 200mg Tablets: PL 00063/0388 P
Nurofen 200mg Caplets: PL 00063/0386 P
Date of revision: March 2017

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PRINTING READS This Way

TDD1022/5

150mm

240mm

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- 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.

Check with your pharmacist or your doctor 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 causing joint pain skin changes and other organ disorders)
- are a smoker
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Nurofen may affect or be affected by some other medicines. For example:
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  - have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- There is a risk of renal impairment in dehydrated children and adolescents.

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Tell your doctor if you become pregnant whilst taking Nurofen. Do not take this medicine in the last 3 months of pregnancy. Avoid the use of this medicine in the first 6 months of pregnancy, unless the doctor advises otherwise.
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  - 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)
- **signs of aseptic meningitis** with neck stiffness, headache, feeling sick, being sick, fever or consciousness. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.

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- drop in blood pressure or irregular heart beat
- stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis)
- liver problems

Side effects for which the frequency can not be estimated from available data:

- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- worsening of colitis and Crohn's disease

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5. How to store Nurofen 200mg Tablets and Nurofen 200mg Caplets

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Do not use after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.
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6. Further information

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They also contain: Sucrose, Sodium Citrate, Talc, Croscarmellose Sodium, Stearic Acid, Titanium Dioxide, Silicon Dioxide, Acacia, Carmellose Sodium, Sodium Laurilsulphate, Macrogol and Black Ink (contains Shellac, Iron Oxide Black (E172) and Propylene Glycol).

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Nurofen 200mg Caplets (capsule shaped tablets) are available in packs 4, 12, 16, 24.
Not all pack size are marketed.

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Manufacturer: Reckitt Benckiser Healthcare International Ltd, NG90 2DB.

Product licence number
Nurofen 200mg Tablets: PL 00063/0388
Nurofen 200mg Caplets: PL 00063/0386
Date of revision: March 2017

First Bar FPO Last Bar
Pharmacode Reads This Way
First Bar P Last Bar
P

RB00000

CUSTOMER INFO:
Minimum Point Size = 9.00pt

RB Artwork and Print Specification

Trident Reference No:	RB262215
ZEN Ref:	TR1225259
Action:	D
Brand:	Nurofen
Category:	Adult
Segment Group:	Core Nurofen
Segment:	Ibuprofen 200mg Tablet
Pack Size:	96Pack
Market/Country:	UK
Date:	06/07/17

Artwork Type: IDM Submission

Component Code (2D if applicable):	RB00000
Parent Technical Packaging Specification:	D8036631
Finished Goods Code:	N/A
Supply Point:	RB Nottingham
Pharmacode No/NE:	N/A
Edgemark Position:	N/A

CAD Cam Ref:	N-Lft-FB-D8036631-150x240mm
Printer:	Multi Packaging Solutions (Tewkesbury, UK)
Substrate:	Paper White

Technical & Non Printing Items
Cutter | Cutter 2 (if applicable)
Guides | Guides 2 (if applicable)

Colours (Leaflet)
Process Black 1 LTH

BARCODE INFO

Barcode Type:	N/A
Barcode Number:	N/A
Magnification:	N/A
Truncated By:	N/A
Full Height:	N/A
Bar Height (Smallest Bar):	N/A
BWR:	N/A
Encoded Data:	N/A

rb
HEALTH ▸ HYGIENE ▸ HOME

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Please note that any low resolution paper Canon colour copies associated with this job should be referred to for content, layout and colour separation only.

STUDIO USE ONLY Alan Smith v2.0
Sm•Art check results: G=1; O=0; R=0; - AS - 06/07/17 16:21:58

ARTWORK APPROVAL

Approved by Sonoco Trident on behalf of Reckitt Benckiser
Signed: _____
Date: _____
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