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NUROFEN®

Pain Relief
Max Strength 512mg Tablets
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 Pain Relief Max Strength 512mg Tablets 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 Pain Relief Max Strength 512mg Tablets are and what they are used for
2. Before you take Nurofen Pain Relief Max Strength 512mg Tablets
3. How to take Nurofen Pain Relief Max Strength 512mg Tablets
4. Possible side effects
5. How to store Nurofen Pain Relief Max Strength 512mg Tablets
6. Further Information

1. What Nurofen Pain Relief Max Strength 512mg Tablets are and what they are used for

The active ingredient (which makes this 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 Pain Relief Max Strength 512mg Tablets are used for the relief of fever and mild to moderate pain, such as:
- headaches and migraine pain
- nerve pain, backache, period pain, rheumatic and muscular pain
- cold and Flu symptoms, sore throat
- dental pain
- the pain associated with non serious arthritis

2. Before taking Nurofen Pain Relief Max Strength 512mg Tablets

Do not take Nurofen Pain Relief Max Strength 512mg Tablets if you:
- are allergic to ibuprofen or any of the other ingredients (see section 6) or to aspirin or other painkillers
- have (or have had two or more episodes of) 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)
- have severe liver or kidney problems
- have severe heart problems
- are in the last 3 months of pregnancy

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, high blood pressure 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.
- are on a diet restricting your salt intake.

Taking other medicines
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
- as anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- to stimulate your heart (e.g, glycosides)
- to 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 Pain Relief Max Strength 512mg Tablets belongs to a group of medicines which may **impair fertility in women.** This is reversible on stopping the medicine. It is unlikely that Nurofen Pain Relief Max Strength 512mg Tablets, 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 of 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 kidney problems in dehydrated children and adolescents

Pregnancy and breast feeding
Do not take in the last 3 months of pregnancy.
Speak to your doctor before taking this medicine if you are in the first 6 months of pregnancy or if you are breastfeeding.

Important information about some of the ingredients of Nurofen Pain Relief Max Strength 512mg Tablets.
Each tablet contains approximately 2.12mmol of sodium.
This quantity is equivalent to 48.6mg of sodium.
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.

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3. How to take Nurofen Pain Relief Max Strength 512mg Tablets

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 and adolescents between 12 and 18 years:
Take 1 tablet with water, up to three times a day as required.
Leave at least four hours between doses. Do not take more than 3 tablets in 24 hours.
Do not give to children under 12 years.
Do not take this medicine for longer than 10 days unless your doctor tells you to.
If symptoms persist or the pain worsens, or if any new symptoms occur, consult your doctor or pharmacist.
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.
If you have taken more Nurofen Pain Relief Max Strength 512mg 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 Nurofen Pain Relief Max Strength 512mg Tablets
Do not take a double dose to make up for a missed dose.
Simply refer to the directions above on how to take the medicine and do not take more than is advised.

4. Possible side effects

Nurofen Pain Relief Max Strength 512mg Tablets are generally well tolerated by most people. However side effects may occur.
STOP TAKING the medicine and seek immediate medical help if you develop:
- **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 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 disorientation. 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 the following uncommon side effects: which may affect 1 to 10 users in 1000:
- 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 may affect 1 to 10 users in 1000:
- allergic reactions, such as skin rashes (urticaria), itching, peeling
- headaches

Rare side effects which may affect 1 to 10 users in 10000:
- flatulence (wind), diarrhoea, constipation and vomiting

Very rare side effects which may affect less than 1 user in 10000:
- 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 cannot 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 Pain Relief Max Strength 512mg Tablets 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Nurofen Pain Relief Max Strength 512mg Tablets

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.
Store in the original pack.

6. Further information

Each tablet contains the active ingredient Ibuprofen 400mg (as Sodium Ibuprofen 512mg).
Also contains: Croscarmellose sodium, Xylitol, Microcrystalline cellulose, Magnesium stearate, Colloidal anhydrous silica, Carmellose sodium, Talc, Acacia spray dried, Sucrose, Titanium dioxide (E 171), Macrogol 6000 powder, and Red ink (contains Shellac, Iron Oxide Red (E 172), Propylene Glycol, Ammonium Hydroxide (E527), Simethicone).
Nurofen Pain Relief Max Strength 512mg Tablets are available in packs of 12 or 24 white, tablets printed with an identifying red logo.
Not all packs will be marketed.
Manufactured by Reckitt Benckiser Healthcare International, 1 Thane Road West, Nottingham NG90 2DB.
Product licence number: PL 00063/0412
Licence holder: Reckitt Benckiser Healthcare (UK) Ltd, Hull, HU8 7DS
Date of revision: February 2018.

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CUSTOMER INFO:
Minimum Point Size = 10.00pt

RB Artwork and Print Specification

Trident Reference No:	RB307354
ZEN Ref:	TR1346378
Action:	C
Brand:	Nurofen
Category:	Adult
Segment Group:	Indication Specific Pain
Segment:	Joint and Back Pain Relief
Pack Size:	24Tablets
Market/Country:	UK
Date:	20/03/18

Artwork Type: IDM Submission

Component Code (2D if applicable):	000000
Parent Technical Packaging Specification:	D0069114
Finished Goods Code:	000000
Supply Point:	RB Nottingham
Pharmacode No/NE:	N/A
Edgemark Position:	N/A
CAD Cam Ref:	N-Lft-FB-D0069114-296x192-Lgc-Reel
Printer:	Generic RB
Substrate:	Paper White

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

Colours (Leaflet)
Process Black

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

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