

NUROFEN®

Back Pain 300mg
SUSTAINED RELEASE CAPSULES



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 Back Pain 300mg Sustained Release Capsules 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 10 days.

If any side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Nurofen Back Pain 300mg Sustained Release Capsules 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 Back Pain 300mg Sustained Release Capsules is used for the relief of:

- backache
- rheumatic pain
- muscular pains

2. Before taking Nurofen Back Pain 300mg Sustained Release Capsules

Do not take Nurofen Back Pain 300mg Sustained Release Capsules 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)
- are taking other NSAID painkillers or more than 75mg aspirin a day
- 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...)

Some medicines may affect or be affected by treatment with ibuprofen.

Avoid taking this product with corticosteroid tablets, quinolone antibiotics or drugs that are prescribed:

- to thin your blood or prevent clotting (e.g. warfarin),
- to stimulate your heart (e.g. glycosides) or treat high blood pressure,
- 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 pregnancy termination (e.g., mifepristone)
- for HIV treatment (e.g., zidovudine)

Speak to your pharmacist or doctor before taking ibuprofen with other medicines

Other warnings

- Nurofen Back Pain 300mg Sustained Release Capsules belongs to a group of medicines which may **impair fertility in women**. This is reversible on stopping the medicine. It is unlikely that Nurofen Back Pain 300mg Sustained Release Capsules, used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Medicines such as Nurofen Back Pain 300mg Sustained Release Capsules may be associated with a **small increased risk of heart attack or stroke**. Any risk is more likely with high doses or prolonged treatment. **Do not exceed the recommended dose.**
- **If you have heart problems, previous stroke or think that you might be at risk of these conditions** (for example if you have high blood pressure, diabetes, or high cholesterol or are a smoker), you should discuss your treatment with your doctor or pharmacist.

Pregnancy and breast feeding

Do not take in the last 3 months of pregnancy or if you are breastfeeding.

Speak to your doctor if you are in the first 6 months of pregnancy.

3. How to take Nurofen Back Pain 300mg Sustained Release Capsules

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 aged 12 years and older:

Take 1 or 2 capsules with water, up to twice a day as required. Do not chew or suck the capsules. Leave at least 8 hours between doses. Do not take more than 4 capsules in 24 hours.

Do not give to children under 12 years.

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 Back Pain 300mg Sustained Release Capsules 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 forgot to take Nurofen Back Pain 300mg Sustained Release Capsules.

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

4. Possible side effects

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 skin reaction (rashes, itchiness, peeling, flaking or blistering)
 - swelling of your face or throat

Tell your doctor if you experience:

- fever, flu-like symptoms, sore throat, mouth ulcers, headache, a stiff neck, vomiting, unexplained bleeding and bruising, severe exhaustion.
- indigestion, stomach or abdominal pain, constipation, diarrhoea, flatulence or if you feel sick, chest pain or fast, irregular heart beat.
- liver and kidney problems associated with swelling in your arms and legs.

Medicines such as Nurofen Back Pain 300mg Sustained Release Capsules may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. (See Section 2 'Other warnings'.)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Nurofen Back Pain 300mg Sustained Release Capsules

Keep all medicines out of the reach and sight 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.

6. Further information

Each capsule contains the active ingredient Ibuprofen 300mg.

They also contain: Sucrose and Maize starch microgranules, Polymers of Methacrylic Acid Esters, Povidone, Polymers of Acrylic and Methacrylic Acid Esters, Talc, Colloidal Silica, Gelatine, Iron Oxide Ink (E172).

Nurofen Back Pain 300mg Sustained Release Capsules are available in packs of 12, 24, 28, 30, 36, 56, 60 in blister strips.

Not all pack sizes will be marketed.

Marketing Authorisation Holder:

Reckitt Benckiser Healthcare (UK) Ltd, SL1 4AQ.

Manufacturer:

Reckitt Benckiser Healthcare International Ltd, NG90 2DB.

Product licence number: Nurofen Back Pain 300mg

Sustained Release Capsules:

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