

- This medicine can only be used for the short term treatment of acute, moderate pains which is not relieved by paracetamol, ibuprofen or aspirin alone (such as rheumatic and muscular pain, backache, migraine, headache, neuralgia, period pain and dental pain)
- You should only take this product for a maximum of three days at a time. If you need to take it for longer than three days you should see your doctor or pharmacist for advice
- This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it
- If you take this medicine for headaches for more than three days it can make them worse

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR MEDICINE

It contains important information.

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.

1. What Nurofen Plus is and what it is used for

The active ingredients (which make Nurofen Plus work) are Ibuprofen and Codeine phosphate.

Ibuprofen 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. **Codeine** is a painkiller (analgesic) that reduces the communication of pain messages.

- Nurofen Plus is for the short term treatment of acute, moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone, such as:
 - migraine, headaches, neuralgia
 - period, dental, back, rheumatic and muscular pains.

2. Before taking this medicine Do not take:

 This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it

If you take a painkiller for headaches for more than three days it can make them worse

- If you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- If you have breathing difficulties
- If you are allergic to ibuprofen, codeine or any of the other ingredients (see section 6) or to aspirin or other painkillers
- If you suffer from severe kidney, heart problems
- If you suffer from chronic constipation
- If you have had gastrointestinal bleeding or perforation when previously taking NSAIDs
- If you have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines
- If you are taking other NSAID painkillers or aspirin with a daily dose above 75mg
- If you are in the last 3 months of pregnancy
- If you are under 12 years old.

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

- have or have had asthma
- have kidney, heart, liver or bowel problems
- have low or high blood pressure
- have a head injury or raised intracranial pressure
- suffer from a thyroid disorder
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders
- have high cholesterol
- have had a heart attack or stroke
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- are a smoker
- are in the first 6 months of pregnancy.

Can you take Nurofen Plus with other medicines?

Some anticoagulant medicines (i.e. thin blood/prevent clotting e.g. aspirin/acetylsal icylic acid, wararin, ticlopidine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagoniss such as losartan), and other medicines may affect or be affected by treatment with ibuprofen.

Medicines called Monoamine oxidase inhibitors (MAOIs) for the treatment of depression may affect or be affected by treatment with codeine.

You should therefore always seek the advice of your doctor or pharmacist before you take Nurofen Plus wih other medicines.

Other warnings

• Nurofen Plus belongs to a group of medicines which may impair fertility in women. This is revesible on stopping the medicine. It is unlikely that Nurofen Plus, used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.

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 Medicines such as Nurofen Plus 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

or take for longer than necessary to control

your symptoms (3 days) If you have heart problems, have had a stroke or think that you might be at risk of these conditions (for example if you have high blood pressure,

diabetes, high cholesterol or are a smoker), you should discuss your treatment with your doctor or pharmacist. Pregnancy and breastfeeding

Do not take in the last 3 months of pregnancy. Speak to your doctor if you are in the first 6 months of pregnancy or are breastfeeding. Usually it is safe to take Nurofen Plus while

breast feeding as the levels of the active ingredients of this

medicine in breast milk are too low to cause your baby any

problems. However, some women who are at increased risk of developing side effects at any dose may have higher levels in their breast milk. If any of the following side effects develop in you or your baby stop taking this medicine and

seek immediate medical advice; feeling sick, vomiting, constipation, decreased or lack of appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

This product may cause drowsiness or dizziness. If affected, do not drive or operate machinery. 3. How to take Nurofen Plus Do not take for more than 3 days. If you

Driving and using machines

and older:

need to use this medicine for more than three days you must speak to your doctor or pharmacist

Adults, the elderly and children aged 12 years

-Swallow 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 any 24 hour period. Do not give to children under 12 years.

-Do not take for 'onger than 3 days unless your doctor tells you to. If symptoms persist or the pain or fever worsen, or if any nev symptoms occur, consult your

doctor or pharmacist This product is for short term use only. You should

take the lowest dose for the shortest time necessary to relieve your symptoms This medicine contains codeine and can cause addiction if you take it continuously for more than three days. When you stop

taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms 4. Possible side effects

Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should seek advice from your doctor, pharmacist or other healthcare professional.

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side-effects via the internet at www.yellowcard.gov.uk; alternatively you can call Freephone 0808 100 3352 (available between 10am-2pm Monday - Friday) or fill in a paper form available from your local pharmacy.

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 rare but serious allergic reaction such as severe skin rashes, peeling, flaking or blistering skin, facial

swelling, unexplained wheezing, shortness of breath, easy Tell your doctor if you experience:

indigestion or heartburn constipation, stomach pain or other abnormal stomach

symptoms rashes, itching or worsening of asthma

- sweating, thirst, muscle weakness or tremors, sleeplessness chest pain or fast, irregular heart beat
- liver and kidney problems

 headache, nausea, dizziness or drowsiness. Medicines such as Nurofen Plus may be associated with a

stroke. How do I know if I am addicted? If you take the medicine according to the instructions on

the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is

important that you talk to your doctor: You need to take the medicine for longer periods of You need to take more than the recommended dose

small increased risk of heart attack (myocardial infarction) or

 When you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again

5. How to store NUROFEN PLUS Keep out of the sight and reach of children.

Do not use Nurofen Plus after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that Store in a dry place below 25°C. Store in the original pack.

6. Further information

Each tablet contains the active ingredients Ibuprofen 200mg and Codeine phosphate 12.8mg. Also contains

microcrystalline cellulose, sodium starch glycollatre, starch pregelatinised, hypromellose, opaspray white M-1-17111 B and talc. Available in blister packs of 6, 8, 12, 16, 18, 24 or 32

white, torpedo-shaped tablets embossed with the N+symbol. Manufacturer:

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