

PACKAGE LEAFLET: INFORMATION FOR THE USER

NEOFEN

200 mg film-coated tablets

IBUPROFEN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What NEOFEN is and what it is used for
2. Before you take NEOFEN
3. How to take NEOFEN
4. Possible side effects
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1. WHAT NEOFEN IS AND WHAT IS IT USED FOR

This medicine contains ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which act to relieve pain and reduce swelling. It can be used to relieve headaches, rheumatic and muscular pain, backache, migraine, period pain, dental pain and neuralgia. It can also be used to reduce fever and relieve the symptoms of colds and flu.

2. BEFORE YOU TAKE NEOFEN

This medicine can be taken by adults and children aged 12 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

Do not take NEOFEN:

- **If you have a stomach ulcer, perforation or bleeding**, or have had one twice or more in the past
- **If you have had perforation or a bleeding stomach** after taking a non-steroidal anti-inflammatory medicine (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)

- **If you are allergic** to ibuprofen or any other ingredients of the product, aspirin or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- **If you are taking aspirin with a daily dose above 75 mg**, or other non-steroidal anti-inflammatory medicines
- **If you have severe heart, kidney or liver failure**
- **If you have an intolerance to some sugars**, unless your doctor tells you to (this medicine contains lactose)
- **If you are pregnant**, and in the last 3 months of pregnancy

Talk to your pharmacist or doctor:

- If you have asthma, a history of asthma or other allergic disease, bowel problems, ulcerative colitis, Crohn's disease
- If you have other kidney, heart or liver problems (see "Do not take")
- If you have a connective tissue disorder such as SLE (Systemic Lupus Erythematosus)
- If you have chickenpox
- If you are elderly – you may get more side effects (see back of leaflet)
- If you are taking any other painkillers or receiving regular treatment from your doctor
- If you have had a stroke, or have heart problems, high blood pressure, diabetes, high cholesterol, or you smoke – see '**Risk of heart attack or stroke**' below
- If you are pregnant, and in the first 6 months of pregnancy
- If you are breastfeeding

Other important information

Risk of heart attack or stroke: Ibuprofen may increase the risk if you take large amounts for a long time. The risk is small. Take the lowest amount for the shortest possible time to reduce this risk.

Woman of childbearing age: If you take this medicine, it may reduce your ability to become pregnant. This effect will be reversed when you stop taking the medicine.

If you take other medicines

Before you take these tablets, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

Other pain killers (including NSAIDs)

Aspirin 75 mg (to prevent heart attacks or strokes) – the protection may be reduced when you take ibuprofen
Medicines to thin your blood (e.g. warfarin)

Mifepristone (for termination of pregnancy) – do not take ibuprofen if you have taken mifepristone in the last 12 days

Water tablets (diuretics), medicines to treat high blood pressure, medicines for heart problems

Corticosteroids, lithium, methotrexate, zidovudine

Quinolone antibiotics (for infections)

Medicines for depression (including SSRIs)

Ciclosporin or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

3. HOW TO TAKE NEOFEN

Check the foil is not broken before first use. If it is, do not take that tablet.

Adults and children of 12 years and over: Take one or two tablets every 4 hours, if you need to.

Don't take more than 6 tablets in 24 hours.

Take the lowest amount for the shortest possible time to relieve your symptoms.

Swallow each tablet with water

Do not give to children under 12 years.

Do not take more than the amount recommended above.

If your symptoms worsen at any time, talk to your doctor.

If your symptoms do not go away within 10 days, talk to your doctor.

If you take too many tablets: Talk to a doctor straight away. Take your medicine and this leaflet with you.

4. POSSIBLE SIDE EFFECTS

Most people will not have problems, but some may get some.

If you are elderly you may be more likely to have some of these side effects.

If you get any of these serious side effects, stop taking the tablets. See a doctor at once:

You are sick and it contains blood or dark particles that look like coffee grounds

Pass blood in your stools or pass black tarry stools

Tiredness or severe exhaustion, changes in the blood which may cause unusual bruising or unexplained bleeding and an increase in the number of infections that you get (e.g. sore throats, mouth ulcers, flu-like symptoms including fever)

Stomach problems including pain, indigestion or heartburn

Unexplained wheezing (asthma), worsening of existing asthma, difficulty in breathing, swelling of the face, tongue, neck or throat, fast heart rate, feeling faint or dizzy or collapse (severe allergic reactions)

Allergic skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, blistering and lesions of the skin)

Worsening of existing severe skin infections (you may notice a rash, blistering and discolouration of the skin, fever, drowsiness, diarrhoea and sickness), or worsening of other infections including chicken pox or shingles

Meningitis (e.g. stiff neck, fever, disorientation)

High blood pressure, heart failure (you may be tired, have difficulty breathing or swollen legs)

A small increased risk of heart attack or stroke if you take large amounts for a long time

Yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems)

Swellings or ulcers of the stomach

Kidney problems, which may lead to kidney failure (you may pass more or less urine, have blood in the urine or cloudy urine, or feel breathless, very tired or weak, have no appetite, or have swollen ankles)

If you get any of the following side effects see your pharmacist or doctor:

Uncommon, feeling sick or rarely, being sick

Uncommon, headache

Rarely, diarrhoea, constipation, wind, worsening of colitis or Crohn's disease

Frequency not known, swellings or ulcers of the mouth lining, which may cause swelling of the limbs

Reporting of side effects

If you get any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NEOFEN

Do not store above 30°C.

Store in the original package.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton.