

PACKAGE LEAFLET: INFORMATION FOR THE USER

NEOFEN

100 mg/5ml syrup

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 SYRUP is and what it is used for
2. Before you take NEOFEN SYRUP
3. How to take NEOFEN SYRUP
4. Possible side effects
5. How to store NEOFEN SYRUP

1. WHAT NEOFEN SYRUP IS AND WHAT IS IT USED FOR

NEOFEN SYRUP belongs to a group of medicines called anti-inflammatory pain killers. It can be used to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of the spine (ankylosing spondylitis), swollen joints, frozen shoulder, bursitis, tendinitis, tenosynovitis, lower back pain, sprains and strains.

NEOFEN SYRUP can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine. It can also be used for the short term treatment of fever in children over the age of 1 year.

The active ingredient in NEOFEN SYRUP is ibuprofen. Each 5ml spoonful of NEOFEN SYRUP contains 100mg ibuprofen.

2. BEFORE YOU TAKE NEOFEN SYRUP

If the answer to any of the following questions is 'YES' please tell your doctor or pharmacist BEFORE taking any NEOFEN SYRUP:

- Are you pregnant or planning to become pregnant, or are you breast-feeding? NEOFEN SYRUP may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

- Are you sensitive (allergic) to any of the ingredients in the syrup? Some people may be sensitive to the E110 or sodium benzoate and if you develop an unexpected rash, sore eyes, sore mouth or difficulty breathing whilst taking the medicine stop taking it and contact your doctor for advice.
- Do you have, or have you previously had, a stomach ulcer or other gastric complaint? Do not take NEOFEN SYRUP if you currently have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past.
- Do you have a condition which increases your tendency to bleeding?
- Do you suffer from asthma or have you ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers?
- Do you suffer from liver or kidney disease?
- Do you suffer from heart disease?
Medicines such as NEOFEN SYRUP may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. You should discuss your treatment with your doctor or pharmacist before taking NEOFEN SYRUP if you:
- have heart problems including heart failure, angina (chest pain) or you have had a heart attack, bypass surgery or peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries).
- have any kind of stroke or think that you might be at risk of these conditions (e.g. if you have a family history of heart disease or stroke, high blood pressure, diabetes, high cholesterol or are a smoker).
- Do you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
- Have you been told by your doctor that you have an intolerance to some sugars? Due to the content of sorbitol (70 mg per ml or 2.8 g per dose) and sucrose (660 mg per ml or 26.4g per dose) it is not recommended for those with hereditary fructose intolerance, glucose malabsorption syndrome or sucraseisomaltase deficiency.
- There is a risk of kidney damage in dehydrated children and adolescents.

Can you take Neofen with other medicines?

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlodipine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-11 receptor antagonists such as losartan) and other medicines may affect or be affected by treatment with ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen with other medicines. In particular you should tell your doctor or pharmacist if you are taking any of the following medicines in addition to those mentioned above:

- diuretics (water tablets)
- cardiac glycosides, such as digoxin, used to treat heart conditions
- lithium
- zidovudine (an anti-viral drug)
- steroids (used in the treatment of inflammatory conditions)
- methotrexate (used to treat certain cancers)
- medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (a type of antibiotic)
- mifepristone
- any other ibuprofen, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including aspirin
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- Gingko biloba herbal medicine (there is a chance you may bleed more easily If you are taking this with ibuprofen).

Other information about NEOFEN SYRUP

The syrup contains small amounts of glycerin (glycerol). In high doses, glycerin may sometimes cause headache, stomach upset and diarrhoea. As such, you should not take more than the stated dose unless your doctor advises you to.

Pregnancy and breast-feeding

The use of NEOFEN SYRUP whilst pregnant or breast feeding should be avoided. NEOFEN SYRUP should not be used in late (the last three months of) pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Driving and Using Machines

NEOFEN SYRUP may make you feel dizzy or drowsy. If it affects you in this way do not drive, operate machinery or do anything that requires you to be alert.

3. HOW TO TAKE NEOFEN SYRUP

ALWAYS take NEOFEN SYRUP exactly as your doctor has told you. If you are not sure refer to the label on the carton or check with your doctor or pharmacist. Ensure the bottle is thoroughly shaken before use. Take with or after food.

DOSAGE:

Adults -The usual dosage is 4 to 6 spoonfuls (5 ml) taken three times a day. Your doctor may choose to increase or decrease this depending on what you are being treated for; but no more than 24 spoonfuls (120 ml/2400 mg) should be taken in one day.

Children - NEOFEN SYRUP should **NOT** be taken by children weighing less than 7 kg. When used to treat fever, the syrup should not be used long term or given to children under the age of 1 year.

The usual dose in children is 20 mg per kg of bodyweight each day, in divided doses. This can be given as follows:

1-2 years: One 2.5 ml (50 mg) dose three/four times a day

3-7 years: One 5 ml (100 mg) dose three/four times a day

8-12 years: Two 5 ml (200 mg) doses three/four times a day

The doctor may choose to increase this dose in children with juvenile rheumatoid arthritis. This dose should not exceed 40mg/kg bodyweight daily in divided doses.

IF YOU TAKE MORE NEOFEN SYRUP THAN PRESCRIBED (AN OVERDOSE) you should contact a doctor or go to the nearest hospital casualty department **IMMEDIATELY** taking your syrup with you.

IF YOU FORGET TO TAKE YOUR NEOFEN SYRUP take it as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Never double up on a dose to make up for the one you have missed.

4. POSSIBLE SIDE EFFECTS

As with all medicines, NEOFEN SYRUP may cause side effects, although they are usually mild and not everyone will suffer from them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist. You can minimise the risk of side effects by taking the least amount of syrup for the shortest amount of time necessary to control your symptoms.

If you suffer from any of the following at any time during your treatment STOP TAKING NEOFEN SYRUP and seek immediate medical help:

- Severe headache, high temperature, stiffness of the neck or intolerance to bright light
- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
-

TELL YOUR DOCTOR AND STOP TAKING NEOFEN SYRUP IF YOU EXPERIENCE:

- Unexplained stomach pain or other abnormal stomach symptoms, indigestion, heartburn, feeling sick *and/or* vomiting.
- Unexplained wheezing, shortness of breath, skin rash, itching or bruising.
- Yellowing of the eyes and/or skin.
- Severe sore throat with high fever.
- Blurred or disturbed vision or seeing/hearing strange things.
- Fluid retention (e.g. swollen ankles).

Medicines such as NEOFEN SYRUP have been associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Blood disorders, kidney problems, liver problems or severe skin reactions may occur rarely with ibuprofen. Very rarely NEOFEN SYRUP may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

Other side effects may include headache, hallucinations, dizziness, tingling of hands and feet, ringing in the ears, depression, confusion, difficulty sleeping, anxiety, impaired hearing, a temporary sensation of burning in the mouth or throat, diarrhoea, constipation, flatulence (wind), unexpected sensitivity of the skin to the sun, tiredness, malaise, mood swings and swelling and irritation inside the nose.

Neofen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

5. HOW TO STORE NEOFEN SYRUP

Your NEOFEN SYRUP should be stored at normal room temperature (below 25°C) and protected from direct light. It should be kept in a safe place out of the reach and sight of children as your medicine could harm them. It should be kept in its original packaging. Do **NOT** take NEOFEN SYRUP after the 'expiry' date shown on the bottle. Once the bottle is opened, the NEOFEN SYRUP must be used within 12 months.

If your doctor decides to stop your treatment, return any leftover product to your pharmacist.

Only keep it if your doctor tells you to.