

PACKAGE LEAFLET: INFORMATION FOR THE USER

NAKLOFEN

50 mg Gastro –resistant tablets

DICLOFENAC SODIUM

• 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 NAKLOFEN is and what it is used for
2. Before you take NAKLOFEN
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1. WHAT NAKLOFEN IS AND WHAT IS IT USED FOR

Diclofenac sodium, the active ingredient in NAKLOFEN, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

NAKLOFEN tablets relieve pain, reduce swelling and ease inflammation in a number of conditions affecting the joints and muscles:

- Rheumatoid arthritis, osteoarthritis, acute gout (painful inflammation of the joints especially in the feet and hands), ankylosing spondylitis (form of spinal arthritis).
- Backache, sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures
- Conditions affecting the tendons for example, tendonitis, tenosynovitis, bursitis.

They are also used to treat pain and inflammation associated with dental and minor surgery.

2. BEFORE YOU TAKE NAKLOFEN

Do not use NAKLOFEN if:

- you are allergic (hypersensitive) to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or any of the other ingredients of NAKLOFEN tablets

- you have established heart disease and/ or cerebrovascular disease, e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages.
- you have or have had problems with your blood circulation (peripheral arterial disease).
- you have a history of allergy to aspirin, ibuprofen or NSAIDs, which includes attacks of asthma, swelling of the nose and throat, face and mouth, skin rashes or a runny nose.
- you have an active or a history of recurrent (more than two) peptic ulcers (ulcer in your stomach or duodenum), bleeding or perforation in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces).
- you have a history of stomach or bowel problems (e.g. gastrointestinal bleeding or perforation) related to the use of NSAIDs.
- you have severe heart, kidney or liver failure
- you are more than six months pregnant

Make sure your doctor knows, before you are given NAKLOFEN if

- you smoke
- you have diabetes
- you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- you are breast-feeding (see section Pregnancy and breast-feeding)

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Take special care

- if you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- if you have kidney or liver problems, or you are elderly
- if you have a condition called porphyria
- if you suffer from any blood or bleeding disorder
- if you ever had asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic pulmonary diseases or infections of the respiratory tract.
- if you have heart problems or you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker)
- if you have Systemic Lupus Erythematosus SLE (inflammatory, auto-immune disorder which causes symptoms such as joint pain, joint inflammation, skin rashes, fever) or any similar condition

Tell your doctor or pharmacist if you have any of these conditions because NAKLOFEN might not be the right medicine for you.

Other special warnings

- You should take the lowest effective dose of NAKLOFEN for the shortest possible time to control symptoms, particularly if you are underweight or elderly.
- You should be aware that medicines such as diclofenac 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. 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.
- Whilst you are taking these medicines your doctor may want to give you a check-up or order a blood test from time to time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Because these are anti-inflammatory medicines, they may reduce the symptoms of infection, for example, headache, and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking NAKLOFEN tablets.
- The 50 mg tablets are not suitable for children aged under 12.

Taking other medicines

Some medicines can interfere with your treatment. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, especially any of the following:

- Medicines to treat diabetes
- Any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen
- Medicines used to treat heart conditions or high blood pressure, for example beta blockers or ACE inhibitors
- Diuretics (water tablets)
- Cardiac glycosides (for example digoxin), used to treat heart problems
- Lithium (used to treat some mental problems)
- Methotrexate (used for treatment of some inflammatory diseases and some cancers)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Trimethoprim (used to prevent or treat urinary tract infections)
- Mifepristone (used to terminate pregnancy) - now or up to 12 days from administration of mifepristone
- Oral steroids (corticosteroids; anti-inflammatory drugs or used as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed)
- Anti-coagulants (blood thinning tablets like warfarin)
- Quinolone antibiotics (for infections)
- Sulfinpyrazone (a medicine used to treat gout) or voriconazole (a medicine used to treat fungal infections)
- Medicines known as SSRIs (used to treat mental disorders such as depression)
- Anti-platelet medicinal products (for example, low dose aspirin) used to prevent blood clots forming (a process called thrombosis)
- Phenytoin (a medicine used to treat seizures)
- Colestipol and cholestyramine (used to reduce high cholesterol)
- Zidovudine (an anti-viral drug)
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Taking NAKLOFEN with food and drink

Take this medicine with or after food

Pregnancy and breast-feeding

- Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take NAKLOFEN tablets during the last 3 months of pregnancy as it may affect the baby's circulation.
- You should advise your doctor or pharmacist if you think you might be pregnant or are up to 6 months pregnant.
- Taking NAKLOFEN tablets may make it more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

You should avoid taking NAKLOFEN whilst breast feeding.

Driving and using machines

Very occasionally people have reported that diclofenac sodium tablets have made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

3. HOW TO TAKE NAKLOFEN

The doctor will tell you how many NAKLOFEN tablets to take and when to take them. Always take NAKLOFEN exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure. Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor. The usual dose is:

Adults and children over 12 years old: 75 to 150 mg daily in two or three divided doses. The recommended maximum daily dose of diclofenac sodium is 150 mg.

Elderly: The lowest effective dose should be used. Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Close surveillance is advisable.
Swallow the tablets whole with a glass of water, with or after food. Do NOT crush or chew the tablets.

If you take more NAKLOFEN than you should

If you, or anyone else, accidentally takes too much NAKLOFEN, tell your doctor or go to your nearest hospital casualty department immediately. Take your medicine pack with you so that people can see what you have taken.

Symptoms of an overdose can include: headache, nausea (feeling sick), vomiting, abdominal pain, stomach or intestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears, fainting, or occasionally convulsions (seizures, uncontrolled fits).

If you forget to take NAKLOFEN

It is important that you do not miss a dose. If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, just take the next dose and forget about the one you missed. DO NOT take a double dose to make up for a forgotten tablet. Do not take more than 150 mg in 24 hours. If you have trouble remembering to take the tablets, tell your doctor or pharmacist.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, NAKLOFEN can cause side effects, although not everybody gets them.

Some side effects can be serious

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

- Pass blood in your faeces (stools/motions). Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
- Swollen face, lips, hands or fingers
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, wheezing or shortness of breath (bronchospasm)
- An unexpected change in the amount of urine produced and/or its appearance.
- Cases of Stevens Johnsons Syndrome and Toxic Epidermal Necrolysis (serious illnesses with blistering of the skin, mouth, eyes and genitals).
- Inflammation of the pancreas (causes symptoms such as severe abdominal pain, back pain, nausea, vomiting).
- Hepatitis (raised levels of enzymes in the blood and symptoms such as abdominal pain, nausea, vomiting).

STOP TAKING NAKLOFEN and tell your doctor if you notice:

- Indigestion or heartburn
- Abdominal pain (pains in your stomach), wind, nausea (feeling sick) or vomiting (being sick) or other abnormal stomach symptoms.
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If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

Effects on the stomach and intestine:

Common side effects (may affect up to 1 in 10 people): nausea (feeling sick), vomiting, diarrhoea, wind, indigestion, heartburn, loss of appetite, abdominal (stomach) pain.

Rare side effects (may affect up to 1 in 1,000 people): gastritis (inflammation of the stomach), any sign of bleeding, for example when emptying your bowels, black tarry stools, blood in your vomit, stomach and/or intestine ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly).

Very rare side effects (may affect up to 1 in 10,000 people): colitis (inflammation of the lower gut which causes symptoms such as abdominal pain, diarrhoea) and worsening of existing ulcerative colitis or Crohn's disease, constipation, inflammation of the mouth (including mouth ulcers), inflammation of the tongue, oesophageal disorders (causes symptoms such as difficulty swallowing and chest or back pains)

Immune system disorders:

Rare side effects (may affect up to 1 in 1,000 people): allergic reactions (see in section 4 "Some side effects can be serious"), anaphylactic and anaphylactoid reactions (serious allergic reaction which causes symptoms such as fast throbbing heart beat, flushing, dizziness, fainting, difficulty breathing).

Very rare side effects (may affect up to 1 in 10,000 people): angioedema (serious allergic reaction which causes swelling mainly of the face, lips, tongue, throat).

Effects on the heart or chest:

Very rare side effects (may affect up to 1 in 10,000 people): heart attack ('myocardial infarction'), chest pain, palpitations (fast or irregular heart beat), heart failure.

Effects on the vascular system:

Rare side effects (may affect up to 1 in 1,000 people): low blood pressure which may include faintness, giddiness or light headedness.

Very rare side effects (may affect up to 1 in 10,000 people): high blood pressure, inflammation of blood vessels.

Effects on the kidneys:

Very rare side effects (may affect up to 1 in 10,000 people): abnormal kidney function or failure causing swelling, particularly of the ankles (fluid retention), high or low blood pressure, presence of blood or protein in the urine, an unexpected change in the amount of urine produced and/or its appearance.

Effects on the liver:

Common side effects (may affect up to 1 in 10 people): elevated liver enzymes in the blood (shows up in blood tests).

Rare side effects (may affect up to 1 in 1,000 people): abnormal liver function, including hepatitis and jaundice (yellowing of the skin and the whites of the eyes).

Very rare side effects (may affect up to 1 in 10,000 people): rapidly progressive hepatitis, liver failure.

Effects on the nervous system:

Common side effects (may affect up to 1 in 10 people): headaches, dizziness.

Rare side effects (may affect up to 1 in 1,000 people): drowsiness, tiredness.

Very rare side effects (may affect up to 1 in 10,000 people): tingling or numbness in the hands and/ or feet, loss of memory, fits, anxiety, shaking, change in sense of taste, sleeplessness, stroke, non-infectious meningitis (particularly if you suffer from auto-immune disorders such as Systemic Lupus Erythematosus (SLE)) with symptoms such as stiff neck, headache together with a dislike of bright lights, feeling sick, vomiting, fever or disorientation, disturbances in sensation.

Psychiatric disorders:

Very rare side effects (may affect up to 1 in 10,000 people): disorientation, mood changes, depression, difficulty sleeping, nightmare, irritability, mental disorders.

Effects on hearing:

Common side effects (may affect up to 1 in 10 people): Vertigo (sensation of irregular or spinning motion).

Very rare side effects (may affect up to 1 in 10,000 people): ringing in the ears, hearing loss or impairment.

Effects on vision:

Very rare side effects (may affect up to 1 in 10,000 people): blurred or double vision, partial or complete loss of eyesight.

Effects on the blood:

Very rare side effects (may affect up to 1 in 10,000 people): blood disorders (including anaemia) resulting in unexplained or unusual bruising or bleeding, pinpoint red spots, fever, sore throat, mouth ulcers, extreme pallor or weakness.

Effects on the skin:

Common side effects (may affect up to 1 in 10 people): rash or spots.

Rare side effects (may affect up to 1 in 1,000 people): hives (redness and swelling of the skin), itching.

Very rare side effects (may affect up to 1 in 10,000 people): purplish spots or patches and flaking or blistering of the skin, itching, eczema (inflammatory skin disease), redness of the skin, photosensitivity (increased sensitivity to sunlight), loss of hair.

Effects on the respiratory system:

Rare side effects (may affect up to 1 in 1,000 people): asthma, difficulty and/or shortness of breath.

Very rare side effects (may affect up to 1 in 10,000 people): pneumonitis (inflammation of the lungs which causes breathlessness, cough and raised temperature).

General disorders:

Rare side effects (may affect up to 1 in 1,000 people): oedema (water retention leading to swelling of the hands, ankles or feet).

Other side effects that have also been reported include (frequency cannot be estimated from the available data):

Impotence, throat disorders, hallucinations, confusion, general feeling of discomfort, inflammation of the nerves of the eyes.

Do not be alarmed by this list - most people take Diclofenac Sodium Tablets without any problems.

If any of the side effects becomes serious, or if you notice side effects not listed in this leaflet, please tell your doctor. He/she may want to give you a different medicine.

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.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE NAKLOFEN

Keep out of the reach and sight of children.

Do not use NAKLOFEN tablets after the expiry date which is printed after 'Exp' on the carton.

Do not store above 25°C. Keep the tablets in their original pack.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.