PACKAGE LEAFLET: Information for the patient

PRONAX

Film-coated tablets – 250 mg, 500 mg

(Naproxen)

Read all of this leaflet carefully before you start taking this medicine.

- 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 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.

In this leaflet:

1. WHAT PRONAX IS AND WHAT IT IS USED FOR

Pronax contains the active substance naproxen which belongs to a group of medicines called nonsteroidal antiinflammatory drugs (NSAIDs). It has antiinflammatory, analgesic, and antipyretic properties.

Pronax is indicated for the treatment of:

- pain and inflammation in rheumatic disease (including juvenile idiopathic arthritis) and other musculoskeletal disorders;
- dysmenorrhoea;
- acute gout.

2. BEFORE YOU TAKE PRONAX

Do not take Pronax if you:

- are hypersensitive to naproxen or to any of the excipients mentioned in this leaflet (see section 6);
- have a history of hypersensitivity to aspirin or any other nonsteroidal antiinflammatory drugs (NSAIDs), which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID;
- have severe hepatic and renal failure (naproxen is contraindicated in patients with baseline creatinine clearance less than 30 ml/minute);
- have severe cardiac failure;
- are in the last trimester of pregnancy;
- have had previous or active acute peptic ulcer or gastrointestinal bleeding;
- are also taking other NSAIDs (including aspirin).

Take special care with Pronax

Ask your doctor before you take Pronax.

The lowest effective dose of NSAIDs should be prescribed for the shortest period to control symptoms and the need for long-term treatment should be reviewed periodically.

It is preferable to avoid NSAIDs in patients with active or previous gastro-intestinal diseases e.g. ulceration / gastrointestinal bleeding, ulcerative colitis, Crohn's disease etc. and to withdraw them if gastro-intestinal lesions develop. Nevertheless, patients with serious rheumatic diseases (e.g. rheumatoid arthritis) are usually dependent on NSAIDs. For this reason, patients at risk of gastro-intestinal ulceration (including the elderly) who need NSAID treatment, should receive gastroprotective treatment.

NSAIDs should be used with caution in the elderly because of the increased risk of side effects and fatalities.

NSAIDs should be used with caution also in patients with:

- hepatic impairment (as there is an increased risk of gastro-intestinal bleeding and fluid retention);

- renal impairment (the lowest effective dose should be used for the shortest possible duration, and renal function should be monitored);
- cardiac impairment (caution is required since NSAIDs may impair renal function);
- hypertension, ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease, heart failure or with risk factors for cardiovascular diseases (e.g. high level of lipids in blood, diabetes, smoking etc.);
- systemic lupus erythematosus or other connective-tissue disorders;
- asthma, other breathing problems or nasal polyps;
- allergic disorders;
- coagulation defects;
- haemorrhagic disorders;
- infections (since symptoms such as fever and inflammation may be masked).

Long-term use of some NSAIDs is associated with reduced female fertility, which is reversible on stopping treatment.
Non-selective NSAIDs are associated with a small increased risk of thrombotic events even when used short-term in those with no cardiovascular risk factors.
The combination of a NSAID and low-dose aspirin can increase the risk of gastro-intestinal side effects. This combination should be used only if absolutely necessary and the patient should be monitored closely.
Withdrawal of naproxen tablets for 72 hours before any blood or urine test is recommended, as they may interfere with the results.
Patients undergoing therapy with some NSAIDs may need to be monitored for the development of blood, kidney, liver or eye disorders.

Taking other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
It is particularly important to inform your doctor that you are taking:
- analgesics, because concomitant use of NSAIDs with other NSAIDs or aspirin increases the risk of side-effects; if you take *aspirin* to prevent blood clots, you should take in consideration

that concomitant treatment with *naproxen* may inhibit this effect; also, concomitant treatment with *ketorolac* should be avoided;

- antibacterials, because of possible increased risk of convulsions when NSAIDs are given with *quinolones;*
- anticoagulants, because of possible enhanced anticoagulant effect of coumarins and *phenindione*; there may be possible increased risk of bleeding when NSAIDs are given with *dabigatran etexilate* or *heparins*;
- antidepressants, because of increased risk of bleeding when NSAIDs are given with SSRIs or *venlafaxine*;
- antidiabetics, because NSAIDs possibly enhance effects of sulfonylureas;
- antivirals, because plasma concentration of NSAIDs are possibly increased by ritonavir; there is increased risk of haematological toxicity when NSAIDs are given with *zidovudine;*
- bisphosphonates, because there is an increased risk of gastrointestinal irritation or renal impairment when *bisphosphonates* are taken with NSAIDs;
- cardiac glycosides, because NSAIDs possibly increase their plasma concentration;
- ciclosporin, tacrolimus because of possible increased risk of nephrotoxicity;
- cytotoxics, because naproxen reduces excretion of methotrexate (increases the risk of toxicity); there is increased risk of bleeding when NSAIDs are given with *erlotinib*; it is advisable to avoid taking NSAIDs in high doses with *mifamurtide* and avoid or take with caution with *pemetrexed;*
- diuretics, which increase the risk of nephrotoxicity of NSAIDs and the diuretic effect is antagonized;
- hydantoins (e.g. phenytoin), because the effects of hydantoins may be enhanced;
- cholestyramine, because it delays the absorption of naproxen;
- corticosteroids, because of the increased risk of gastrointestinal bleeding;
- lithium, because NSAIDs reduce its excretion and increase the risk of toxicity;
- iron chelators (e.g. deferasirox), because of the increased risk of gastrointestinal bleeding;
- mifepristone, because the effect of mifepristone can be decreased by the combination with NSAIDs;
- nicorandil, because the risk for gastrointestinal perforation can be increased;
- pentoxyphylline, because of possible increased risk of bleeding;

- probenecid, which reduces the excretion of naproxen and increases its plasma concentration;
- beta-blockers, adrenergic neurone blockers, calcium-channel blockers, alpha-blockers, ACE-inhibitors, angiotensin-II receptor antagonists, diazoxide, clonidine, methyldopa, moxonidine, nitrates, hydralazine, minoxidil and sodium nitroprusside, because NSAIDs antagonize their hypotensive effect.

Taking Pronax with food and drinks

Taking oral tablets of naproxen with milk or food, may partially reduce symptoms such as dyspepsia.

Pregnancy

If you think you might be pregnant or are planning to have a baby, tell your doctor or pharmacist before taking this medicine.

NSAIDs should not be used during the first two trimesters of pregnancy, unless the potential benefit for the mother outweighs the potential risk to the foetus.

Use of NSAIDs in the last trimester of pregnancy is contraindicated because it causes complications for the baby. In addition, the onset of labour may be delayed and its duration may be prolonged.

Breastfeeding

Tell you doctor or pharmacist if you are breastfeeding.

Naproxen appears in breast milk in small amounts to be harmful. Anyway, the use of NSAIDs should, if possible, be avoided when breastfeeding.

Driving and using machines

Naproxen tablets may cause visual disturbances, dizziness and drowsiness. For this reason, if affected, you should not drive or operate machinery.

3. HOW TO TAKE PRONAX

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Tablets are for oral administration, preferably with or after food.

Rheumatic disease

Adults: the usual dose is 0.5 - 1 g daily taken in 1 - 2 divided doses.
Children over 5 years with juvenile idiopathic arthritis: 5 – 7.5 mg/kg twice daily (maximum 1 g daily).

Acute musculoskeletal disorders and dysmenorrhoea

Adults: the usual starting dose is 500 mg, followed by 250 mg every 6 - 8 hours as required. The maximum daily dose is 1.25 g.
Children over 16 years: 5 mg/kg twice daily (maximum 1 g daily).
It is not recommended in children under 16 years.

Acute gout

Adults: the usual starting dose is 750 mg, followed by 250 mg every 8 hours until attack has passed.
It is not recommended in children under 16 years.

Lower doses should be considered in patients with renal or hepatic impairment and in the elderly. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

If you take more Pronax than you should

If you take more Pronax than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures to be taken.
Overdosage with naproxen is associated with different symptoms such as: nausea, vomiting,

indigestion, heartburn and seizures. Life-threatening adverse effects are uncommon. However, apnea, metabolic acidosis, and impaired renal function have been reported following overdosage of naproxen.
In acute overdosage, the stomach should be emptied immediately by inducing emesis or by gastric lavage. Supportive and symptomatic treatment should be initiated.

If you forget to take Pronax
If you forget to take one dose, take the next dose in its usual time. Do not take a double dose to make up a forgotten dose.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, naproxen can cause side effects, although not everybody gets them.

Gastrointestinal disorders: are the commonest adverse effects of NSAIDs such as: gastrointestinal discomfort, nausea, diarrhea, vomiting, constipation. These are usually mild and reversible but in some patients peptic ulceration and severe gastrointestinal bleeding may occur (especially in the elderly), perforation, melaena (stools with dark colour), haematemesis (vomiting with blood), stomatitis. Pancreatitis, oesophagitis, gastritis and induction or exacerbation of colitis and Crohn's disease have also been reported.

Psychiatric disorders: insomnia, depression, confusion, dream abnormalities and hallucinations.

Nervous system disorders: headache, dizziness, nervousness, drowsiness, aseptic meningitis (especially in patients with connective tissue disorders such as systemic lupus erythematosus), convulsions, inability to concentrate, cognitive dysfunction, paraesthesia.

Ear and labyrinth disorders: hearing disturbances such as tinnitus, vertigo.

Immune system disorders: hypersensitivity reactions such as fever, angioedema, bronchospasm, and rashes.

Eye disorders: visual disturbances, corneal opacity, inflammation of the optic disc (papillitis) and swelling of the optic disc (papilloedema), optic neuritis.

Blood and lymphatic system disorders: anaemia (aplastic and haemolytic), thrombocytopenia, neutropenia, eosinophilia, and agranulocytosis.

Renal and urinary disorders: some NSAIDs have been associated with nephrotoxicity such as interstitial and glomerular nephritis, nephrotic syndrome. Renal failure may be provoked by NSAIDs especially in patients with pre-existing renal impairment. Haematuria, raised serum creatinine and renal papillary necrosis have also occurred. Long-term use of analgesics, including NSAIDs, has been associated with nephropathy.

Cardiac disorders: fluid retention may occur, palpitations and rarely deterioration of heart failure. The use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (e.g. myocardial infarction or stroke).

Vascular disorders: hypertension, vasculitis.

Respiratory, thoracic and mediastinal disorders: alveolitis, pulmonary eosinophilia, dyspnea, asthma and pulmonary oedema.

Skin and subcutaneous tissue disorders: alopecia, erythema nodosum, pustular reaction, photosensitivity, severe skin reactions, Stevens-Johnson syndrome, toxic epidermal necrolysis. If severe skin reactions occur, treatment should be discontinued immediately and the patient should be monitored.

Hepatobiliary disorders: hepatotoxicity.

Musculoskeletal and connective tissue disorders: myalgia and muscle weakness.

Reproductive system disorders: reduction of female fertility.

Metabolic and nutrition disorders: hyperkalaemia.

General disorders: thirst, fatigue and malaise.

Talk to your doctor or pharmacist if you get any of these side effects or any side effect not listed in this leaflet.

5. HOW TO STORE PRONAX

Keep out of the reach and sight of children!
Do not use Pronax after the expiry date which is stated on the package.
Do not store above 25°C!
Keep in the original package to protect it from light.

6. FURTHER INFORMATION

What Pronax contains

The active substance is naproxen.
Pronax 250 mg film-coated tablets:
Each film-coated tablet contains 250 mg naproxen.

Pronax 500 mg film-coated tablets:
Each film-coated tablet contains 500 mg naproxen.

The excipients are:

tablet core: starch, microcrystalline cellulose, povidone, sodium starch glycolate, magnesium stearate, stearic acid
film coat: polyvinyl alcohol, titanium dioxide, macrogol, talc.

Contents of the pack

Pronax 250 mg: box with 30 film-coated tablets.

Pronax 500 mg: box with 20 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

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