

Package leaflet: Information for the patient

Nalgesin S, 275 mg film-coated tablets Naproxen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.
- If any side effects occur, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nalgesin S is and what it is used for
2. What you need to know before you use Nalgesin S
3. How to use Nalgesin S
4. Possible side effects
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1. What Nalgesin S is and what it is used for

Nalgesin S relieves pain, reduces inflammation and lowers fever. The mechanism of action is by inhibiting prostaglandin synthesis.

Tablets are solved quickly and have a rapid onset of action.

Nalgesin S relieves mild and moderate pain (e.g. toothache and headache, pain in muscles, joints and back, menstrual pain).

2. What you need to know before you use Nalgesin S

Do not use Nalgesin S:

- if you are allergic to naproxen or any of the other ingredients of this medicine (listed in section 6).
- if you have gastrointestinal ulceration or other gastrointestinal disease,
- if you ever have had gastric bleeding,
- if you take this medicine concomitantly with other analgesics (acetyl salicylic acid or other nonsteroidal anti-inflammatory drugs),
- if you have severe hepatic or renal impairment,
- if you have severe heart failure,
- during the last trimester of pregnancy,
- to treat pain for more than 3 days without consulting a doctor,

Do not give Nalgesin S to children and adolescents under 16, unless otherwise instructed by a doctor.

Warnings and precautions

Consult your doctor or pharmacist before taking Nalgesin S:

- if you are showing any symptoms of high blood pressure (such as oedema) or clotting disorders (petechiae, haematomas, bleeds)
- if you use other medicines on a regular basis,
- if you visit doctor regularly due to a chronic illness,
- if you have experienced serious side effects resulting from the use of any analgesics,
- please inform your doctor if you develop visual disturbances,

- if you have or ever have had gastrointestinal diseases, you have to be closely observed by your doctor; take special care if you have ulcerative colitis and Crohn's disease, because the disease may return or deteriorate. Serious gastrointestinal side effects may occur even in patients without previous gastrointestinal complaints; there may occur haemorrhage and intestinal perforation (hole in intestinal wall),
- if you have kidney or liver problems.

Stop using Nalgesin S tablets and consult your doctor:

- if you develop new or unexpected symptoms,
- if symptoms persist or worsen,
- if you have difficulty in swallowing,
- if you experience heartburn or stomach pain.

Medicines like Nalgesin S may be associated with somewhat higher risk of having a heart attack (myocardial infarction) or stroke. Any risk is elevated at high doses and during prolonged use. Do not exceed the recommended dose or duration of treatment (3 days for lowering elevated body temperature or 10 days for pain relief).

If you suffer from heart problems or have recently had a stroke or if you think you might have a risk of developing such conditions (for example, if you have high blood pressure, diabetes or elevated blood cholesterol level or if you smoke), you must talk to your doctor or pharmacist before taking naproxen. If you take anticoagulants, you may be at risk of haemorrhage when taking Nalgesin S.

If you regularly drink alcohol (three or more glasses a day), consult with your doctor before using Nalgesin S. Concomitant administration of Nalgesin S with alcohol may increase the risk of stomach bleeding.

If you have experienced rash, facial swelling, asthma attack or even shock when taking other analgesic or antipyretic medicines, do not take Nalgesin S without consulting with your doctor. Do not take Nalgesin S if you have severe fresh wounds or upcoming major surgery within the next 48 hours.

Other medications and Nalgesin S

Let your doctor or pharmacist know if you are taking, have recently taken, or are planning to take any other medications.

As a result of concurrent use with some other medications, Nalgesin S may increase or reduce their effect. Interactions with the following medications have been observed:

- other analgesics (acetylsalicylic acid and other non-steroidal anti-inflammatory drugs),
- medications that prevent blood clotting (anticoagulants, fibrinolytics),
- medicines used to prevent thrombus formation (aspirin / acetylsalicylic acid),
- medications used in the management of diabetes (sulphonylurea)
- epilepsy medications (hydantoin derivatives)
- medications for high blood pressure
- medications which increase urine production (furosemide)
- medications used to treat mental disorders (lithium)
- immunosuppressive medications (cyclosporine)
- medications for malignant disorders (methotrexate)
- steroid hormones which are produced in the adrenal cortex (corticosteroids)

Nalgesin S with food and drink

Take the tablets with a small amount of liquid. You may take them before, during, or after a meal.

Pregnancy, breast-feeding, and fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Preclinical studies performed in animals did not show side effects on pregnancy or foetal development. There have been reports of human congenital malformations in connection with NSAIDs, but their incidence is low and does not seem to follow a particular pattern. It is not

recommended to use naproxen during pregnancy. The doctor will decide whether the benefits to the mother outweigh the potential risks to the foetus. Thus, do not take this medicine during pregnancy, unless recommended by your doctor.

Do not take this medicine during the last trimester of pregnancy.

Breast-feeding

Talk to your doctor or pharmacist before taking any medicine. According to limited data from clinical studies, NSAIDs may be excreted in breast milk in very small quantities.

Breast-feeding is not recommended during treatment with Nalgesin S.

Fertility

Using Naproxen may impair fertility, and is therefore not recommended for women who are planning to get pregnant. If you have difficulties with conception or are tested for infertility, tell your doctor.

Driving and using machines

There is no knowledge of naproxen having a significant effect on the ability to drive or use machines.

Nalgesin S contains sodium

This medicine contains 25.079 mg of sodium (the main ingredient in table salt) in one tablet. That is equal to 1.25% of the maximum recommended daily intake of sodium in adults.

3. How to use Nalgesin S

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose is:

Adults and adolescents 16 years and older: 1 tablet in every 8 to 12 hours (maximum 3 times a day), until pain persists. You may take 2 tablets as the first dose of the treatment.

Patients 65 years and older: 1 tablet in every 12 hours (maximum 2 times a day).

Use in children and adolescents

Children and adolescents: do not use Nalgesin S tablets in children under 16 years without consulting a doctor.

Duration of treatment: maximum duration of treatment without consulting a doctor is 3 days.

If you have the impression that the effect of Nalgesin S is too strong or too weak, talk to your doctor or pharmacist.

If you use more Nalgesin S tablets than you should

If you have taken too much Nalgesin S, contact your doctor immediately.

Overdose may result in abdominal pain, nausea, vomiting, dizziness, ringing in the ears, irritability, in more severe cases vomiting blood, blood in stools, disturbances in consciousness, respiratory disorders, convulsions and renal failure.

In case of accidental or deliberate overdose of large quantity of tablets, your doctor will take necessary measures.

If you forget to use Nalgesin S

Do not take a double dose to make up for a forgotten dose.

Take Nalgesin S only if necessary. Never take a double dose.

If you stop taking Nalgesin S

If you take naproxen for short periods and only for pain relief, you may safely stop taking it as soon as you no longer need to take it.

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

4. Possible side effects

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

Possible side effects: abdominal pain, vomiting, nausea, vertigo, dizziness, fatigue, sleep disturbances, ringing in the ears or swelling in the legs. These are all mild side effects, but if you notice them, inform your doctor.

Very rare side effects: gastrointestinal bleeding, facial swelling, rash, asthma attack or fainting. These are serious side effects and need urgent medical aid.

Medicines like Nalgesin S may be associated with elevated risk of heart attack (myocardial infarction) or stroke.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Nalgesin S

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nalgesin S contains

- The active substance is naproxen sodium. One film-coated tablet contains 275 mg naproxen sodium.
- The other excipients are povidone, microcrystalline cellulose, talc, magnesium stearate, hypromellose, titanium dioxide (E171), macrogol, indigotine (E132). See section 2 "Nalgesin S contains sodium".

What Nalgesin S looks like and contents of the pack

Film-coated tablets are oval, slightly biconvex and blue film-coated.

Blister pack and carton contain 10, 20 or 30 film-coated tablets.