

SONAP CAPLET / FORTE CAPLET

Naproxen sodium (275mg, 550mg)

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What Sonap / Sonap Forte is used for

Sonap / Sonap Forte contains the active ingredient naproxen sodium.

Sonap / Sonap Forte is used:

- To treat signs and symptoms of acute gout, dysmenorrhoea (period pain), menorrhagia (heavy and prolonged menstrual period), headache, acute migraine attack.
- To treat signs and symptoms of mild to moderately severe, acute or chronic musculoskeletal and soft tissue inflammation.
- To relief mild and moderate pain including pain after giving birth, pain following IUD insertion (contraceptive coil fitted), pain after operation and pain due to orthopedic surgery.

How Sonap / Sonap Forte works

Naproxen sodium belongs to the group of medicines called non-steroidal anti-inflammatory drug (NSAIDs). It works to reduce pain and inflammation (swelling and redness) by inhibiting the activity of certain hormones.

Before you use Sonap / Sonap Forte

- When you must not use it

- Have ever had a reaction or been told that you are allergic to naproxen sodium or to any of the excipients.
- If you have had asthma, rhinitis (inflammation of the nasal mucous membrane), urticaria (itching or hives) and the symptoms become worsen caused by Aspirin or NSAIDs.
- If you have or have had stomach ulcer or intestinal inflammatory disease.

- Before you start to use it

Tell your doctor if you:

- Have allergies to any other medicines, food, preservatives or dyes
- Have heart problems, high blood pressure and previous stroke
- Have impaired kidney and liver functions
- Have blood cells disorder
- Sonap/Sonap forte may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Sydrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.
- Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- Have or have had ulceration, bleeding and perforation of the stomach and intestinal.
- Are a smoker or alcoholic drinker
- An elderly patient
- Are suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).

If you are not sure whether you should start taking this medicine, consult your doctor.

- Taking other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines and Sonap / Sonap Forte may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Aspirin, acetaminophen or other NSAIDs to relieve pain and swelling
- Methotrexate, used to treat skin problems, arthritis or cancer
- Medicines to stop blood clotting eg. warfarin
- Hydantoin (for epilepsy), like phenytoin
- Antibiotic eg. sulphonamides
- Diabetic drugs eg. sulphonylureas
- Lithium, a medicine used to treat mental illness
- Diuretics, a water tablet such as frusemide
- Probenecid, a medicine to treat gout

- Medicines for high blood pressure eg. propranolol and β -blockers

Naproxen sodium could interfere with the results of laboratory test. Before you have any tests, tell your doctor you are taking this medicine.

This may not be a complete list of all interactions that may occur. Ask your doctor or pharmacist if naproxen sodium may interact with other medicines that you take.

Pregnancy and breast-feeding

Please consult your doctor before start to use Sonap/Sonap forte if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Sonap/Sonap forte against the benefits they expect it will have for you.

How to use Sonap / Sonap Forte

Always take Sonap / Sonap Forte caplets exactly as your doctor has told you.

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults

Muscle, joint or tendon problems, arthritis or pain relief after an operation or coil fitting and period pain:

The recommended dose is 550 mg given initially, followed by 275 mg every 6 to 8 hours as needed. The total dose in one day should not be more than 1375 mg.

Gout:

The starting dose is 825mg, followed by 275 every 8 hours until the gout has gone.

Menorrhagia:

825 – 1375mg per day taken in 2 doses on the first day of menstrual bleeding. The total daily dose should not exceed 1100mg.

Migraine headache:

The recommended dose is 825 mg taken at the first sign of a migraine. An additional dose of 275 mg to 550 mg can be taken at least one hour after the initial dose.

Prevention of migraine headache:

Take 550mg twice daily. A total daily dose of 1375mg should not be exceeded.

Children and adolescents

Sonap / Sonap Forte is not recommended for use in children under 16 years of age.

Elderly and patients with impaired kidney or liver function

Dosage should be reduced.

- When to use it

Take your medicine as directed and the duration of treatment is to be determined by your doctor or pharmacist.

Take Sonap / Sonap Forte at the same time each day.

- How long to use it

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it. It is very important that you do not stop taking this medicine suddenly even if you feel well.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

- If you use too much (overdose)

If you or anyone else takes too many caplets, tell your doctor and go to your nearest hospital emergency department immediately. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining caplets you have with you.

The following symptoms may be observed in overdose:

- Nausea, vomiting, drowsiness

- Abdominal pain, heartburn
- Seizures

While you are using it

- Things you must do

- Always take Sonap / Sonap Forte exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.
- If you become pregnant, or plan on becoming pregnant while taking Sonap / Sonap Forte, tell your doctor immediately.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Sonap / Sonap Forte.

- Things you must not do

- Do not stop taking your medicines without consulting your doctor. It is important to keep taking your medicine even if you feel well.
- Do not use Sonap / Sonap Forte after the expiry date which is stated on the blister and carton.
- Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

• Driving and using machines

As with other NSAID medicines, Sonap / Sonap Forte may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Like many medicines, Sonap / Sonap Forte may cause side effects in some patients, particularly when you are first taking them but not everyone will get it.

Tell your doctor or pharmacist if you notice the following side effects and it worries you:

Gastrointestinal tract

- Bleeding from stomach (seen as vomit which has blood in it) or anus (seen as bloody diarrhea)
- Ulcers or holes forming in the stomach or gut, signs such as stomach upset (heartburn), abdominal pain and nausea (feeling sick)
- Indigestion, epigastric pain and constipation

Nervous system

- Headache, dizzy, feeling tired and sleepy
- Difficulty sleeping, depression, feeling nervous, ringing in the ears
- Muscle pain
- Difficulty in memory and concentration

Allergic reaction

- Swelling of your throat, face, hands or feet
- Difficulty breathing, tightness in your chest
- Skin rashes, blisters or itching

Severe skin rashes

- Severe skin rashes with blisters or peeling of your skin.
- Sweating, skin being more sensitive to the sun

Liver problems

- Yellowing of your skin or eyes (jaundice)
- Feeling tired, loss of appetite, inflamed liver and abnormal liver function tests

Heart problems

- Difficulty breathing, irregular heartbeats, heart failure
- Swelling of the lower limbs
- Inflammation of blood vessels, often with skin rash

Kidney problems

- Kidney failure, blood found in the urine

Others

Hearing impaired and fever

Tell your doctor or pharmacist if you notice anything else that makes you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →

Reporting)

Storage and Disposal of Sonap / Sonap Forte

- Storage

Do not store above 30°C. Keep in the original package to protect from light and moisture.

Do not store Sonap / Sonap Forte or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of the reach of children.

- Disposal

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

Product Description

- What it looks like

Sonap 275mg Caplet is a blue, oval biconvex film coated caplet.

Sonap Forte 550mg Caplet is an opaque violet-blue, oval biconvex film coated caplet with bisect on both sides and embossed with “SPS”, “S13” on one side.

- Ingredients

- Active ingredient

Sonap 275mg Caplet: Each caplet contains naproxen sodium 275mg equivalent to naproxen 250mg.

Sonap Forte 550mg Caplet: Each caplet contains naproxen sodium 550mg equivalent to naproxen 500mg.

- Inactive ingredients

Sonap 275mg Caplet: Croscarmellose sodium, methylene chloride, sodium starch glycolate, corn starch, talcum powder, titanium dioxide, polyethylene glycol 6000, povidone K-90, dimethicone 10%, hypromellose E5 premium, brilliant blue FCF Lake, hypromellose E15 premium, lactose, isopropyl alcohol, sodium lauryl sulfate and purified water.

Sonap Forte 550mg Caplet: Talcum powder, purified water, polyethylene glycol 6000,

isopropyl alcohol, croscarmellose sodium, methylene chloride, erythrosine lake, hypromellose E5 premium, brilliant blue FCF lake, hypromellose E15 premium, ponceau 4R lake, sodium starch glycolate, corn starch, povidone K-90, sodium lauryl sulfate, titanium dioxide, methyl paraben, propyl paraben, lactose monohydrate and dimethicone 10% solution.

- MAL Numbers

Sonap 275mg Caplet
MAL05072030AZ

Sonap Forte 550mg Caplet
MAL06071077AZ

Manufacturer

SRIPRASIT Pharma Co., Ltd.

216 Moo 6, Suanluang, Krathum Baen, Samut Sakhon 74110, Thailand.

Product Registration Holder

IMEKS Pharma Sdn Bhd.

No. 5&9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur, Malaysia.

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15-July-2015

Serial Number

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