

SAFROSYN S TABLET

Naproxen Sodium (275mg, 550mg)

What is in this leaflet

1. What Safrosyn S Tablet is used for
2. How Safrosyn S Tablet works
3. Before you use Safrosyn S Tablet
4. How to use Safrosyn S Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Safrosyn S Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What Safrosyn S Tablet is used for

It contains naproxen sodium which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce inflammation and pain in joints and muscles.

Safrosyn S Tablet is used to treat:

- Musculoskeletal and joints disorders such as ankylosing spondylitis (arthritis of the spine), osteoarthritis (arthritis in joints) and rheumatoid arthritis (autoimmune disease in which your body's immune system, mistakenly attacks your joints and causes inflammation).

Safrosyn S Tablet cannot cure arthritis but is used to give relief of some symptoms such as inflammation, swelling, stiffness and joint pain.

- In mild to moderate pain such as dysmenorrhea (period pain) and migraine.
- Signs and symptoms of acute gout.

How Safrosyn S Tablet works

Safrosyn S Tablet works by blocking the effect of chemicals called cyclooxygenase (COX) enzymes. These enzymes help to make other chemicals in the body, called prostaglandins.

Some prostaglandins are produced at sites of injury or damage, and cause pain and inflammation. By blocking the effect of COX enzymes, fewer prostaglandins are produced, which means pain and

inflammation, are eased.

Before you use Safrosyn S Tablet

- When you must not use it

Do not take Safrosyn S Tablet if you:

- are allergic (hypersensitive) to naproxen, aspirin and other nonsteroid anti-inflammatory drugs
- have serious liver, kidney and heart failure
- In the last trimester of pregnancy
- have active or previous history of recurrent stomach ulcer or bleeding
- Have bleeding or perforation in upper digestive tract
- Children under 2 years of age

Pregnancy and lactation

Do not take Safrosyn S Tablet if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Safrosyn S Tablet if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine if you are breast feeding.

- Before you start to use it

Inform your doctor or pharmacist before taking this medicine if you have:

- restricted sodium intake
- problems of galactose intolerance, the total lactase deficiency or glucosegalactose malabsorption
- Bronchial asthma or allergic disease
- heart problems, high blood pressure and previous stroke
- impaired kidney function and associated health conditions, impaired liver functions and cardiac impairment
- Take steroid, other NSAIDs and medicine to increase production of urine and lower blood pressure
- blood cells disorder
- Safrosyn S Tablet may cause severe skin reaction, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reaction occur, stop use and seek medical assistance right away.

- had ulceration, bleeding and perforation of the stomach and intestinal, especially for elderly and/or debilitated patients
- suffered from dyspepsia (discomfort at the epigastric region due to digestion problem)

If you are not sure if any of the above conditions apply to you, talk to your doctor or pharmacist before using Safrosyn S Tablet

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

If you take Safrosyn S Tablet with other medicines, especially:-

- Probenacid - Concurrent use may leads to toxicity
- Methotrexate - Concurrent use may result in severe or fatal toxicity
- Antihypertensives or diuretic - Concurrent use with NSAID may decrease the diuretic, natriuretic and hypertensive effects of diuretics, probably by inhibiting renal prostaglandin synthesis and increase the risk of renal failure
- Cardiac glycosides - May exacerbate heart and kidney failure as well as lead to glycoside toxicity
- Lithium -May lead to lithium toxicity
- Mifepristone - NSAIDs can reduce the effect of mifepristone
- Corticosteroids- Increased risk GI bleeding and ulcer
- Anti-coagulants - May enhance the effects of anti-coagulants
- Quinolone antibiotics – Increased risk of convulsion
- Tacrolimus – Increased risk of kidney toxicity
- Hydantoin, sulfonamide or sufonylurea – May interact with naproxen
- Anti-platelet agents – May increased risk of GI bleeding

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How to use Safrosyn S Tablet

- 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 of your medicine, ask your doctor or pharmacist for help.

Dose in adults

For analgesia, dysmenorrhea, acute musculoskeletal conditions/ acute pain in which there is an inflammatory component.

The recommended dose is 550mg followed by 275 mg tablet every 6 to 8 hours as required.

For Acute Gout

The recommended starting dose is 825mg followed by 275mg every 8 hours as needed.

For Migraine

For treatment of acute migraine headache, the recommended dose is 825mg at the first symptom of an impending attack. An additional dose of Safrosyn S Tablet 275mg to 550mg can be taken throughout the day, if necessary, but not before half an hour after the initial dose. For prophylaxis of migraine headache, the recommended dose is 550mg twice daily. If no improvement is seen within 4 to 6 weeks, the drug should be discontinued. A total dose of 1375mg per day should not be exceeded.

Dose in children

Not recommended for use in children below 16 years of age.

Your doctor will advise, the lowest effective dose for the shortest possible duration and that the medicine should be used.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Safrosyn S Tablet for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many of Safrosyn S Tablet may cause drowsiness, nausea, vomiting or heartburn.

While you are using it

- Things you must do

Take your medicine exactly as your doctor or pharmacist has told you.

When seeking other treatment, inform all the doctors, dentists and pharmacists that you are taking Safrosyn S Tablet.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Safrosyn S Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Use of Safrosyn S Tablet should be carefully considered in individuals with risk factors for gastrointestinal events.
- Have systemic lupus erythematosus disorders (SLE).
- Safrosyn S Tablet can inhibit platelet aggregation. It should be used with care in individuals with undesirable haemostatic defects.
- Care is required for individuals with

creatinine clearance of less than 20mL/minute, individuals with fluid retention, hypertension or heart failure and individuals receive anticoagulants therapy.

- If this occurs, the medicine should be withdrawn immediately.
- Regular hematologic monitoring for individuals on long-term therapy with Safrosyn S Tablet.

Side effects

Like all medicines, Safrosyn S Tablet can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

- Gastrointestinal disturbances reactions; range from heartburn, discomfort, diarrhoea nausea, vomiting and abdominal pain to serious gastrointestinal bleeding or ulcer.
- Immune system disorder; range from hypersensitivity reactions such as asthma, skin rashes, itchiness, swelling of face, mouth and eyes to severe skin reactions and anaphylaxis.
- Metabolic and nutrition disorder such as hyperkalaemia.
- Difficulties to sleep, dream abnormalities, depression, confusion and hallucinations.
- Nervous system disorder; range from dizziness, headache, convulsion, aseptic meningitis (inflammation in meninges), inflammation of optic nerve and inability to concentrate.
- Central Nervous System-related side effects include headache, dizziness, nervousness, tinnitus (noises in the ears), depression, drowsiness and difficulty sleeping.
- Heart disorder such as irregular heartbeat, high blood pressure and heart failure, myocardial infarction or stroke.
- Vascular disorder such as inflammation of the blood vessels
- Safrosyn S Tablet can provoke breathing difficulties, asthma, inflammation of lung tissue and lung congestion.
- inflammation and toxicity of the kidney which can lead to kidney failure.

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- Inflammation of liver and jaundice (skin and eyes turn yellowish).
- Blood disorder
- Joint disorder such as myalgia (muscle aches and pain)
- The use of the product may lead to female infertility
- The product may cause severe skin reaction, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off.
- General disorders such as swelling, thirst, fever, fatigue and general feeling of discomfort.

Stop taking Safrosyn S Tablet and see a doctor straight away if you notice any of the serious side effects listed above. You may need urgent medical treatment

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Safrosyn S Tablet

- Storage

Keep out of the reach and sight of children.
Store below 30°C. Protect from light.

Do not take Safrosyn S Tablet after the expiry date stated on the label.

- 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

Safrosyn S Tablet 275mg

An oval, blue film-coated tablet with characteristic markings.

Safrosyn S Tablet 550mg

An oblong, blue film-coated tablet with characteristic markings.

- Ingredients

Safrosyn S Tablet 275mg

- Active ingredient(s):

Each tablet contains Naproxen Sodium 275mg

- Inactive ingredient(s):

Lactose monohydrate, Maize starch, Povidon, K30, Sodium starch glycolate, Magnesium stearate, Opadry blue, Denatured ethanol and Purified water.

Safrosyn S Tablet 550mg

- Active ingredient(s):

Each tablet contains Naproxen Sodium 550mg

- Inactive ingredient(s):

Lactose monohydrate, Microcrystalline cellulose, Maize starch, Povidone, Sodium starch glycolate, Magnesium stearate, and Opadry Blue, Denatured ethanol and Purified water.

- MAL number(s):

Safrosyn S Tablet 275mg

MAL19992403AZ

Safrosyn S Tablet 550mg

MAL20020260AZ

Product Registration Holder/

Manufacturer

Pharmaniaga Manufacturing Berhad
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Date of revision

7/3/2025

Serial Number

NPRA(R2/2)250306/1427