

# SUNPROX 550 TABLET

Naproxen sodium ( 550 mg )

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## What Sunprox 550 Tablet is used for

It is used for relief of mild to moderate pain and for the treatment of primary dysmenorrhea (period pain). It also indicates for the treatment of rheumatoid arthritis (systemic inflammatory disorder that affects joints), osteoarthritis (degenerative joint disease) ankylosing spondylitis (chronic inflammatory disease of the skeleton), tendinitis (inflammation of the tendon), bursitis (Inflammation of the bursa) and acute gout.

## How Sunprox 550 Tablet Works

Sunprox 550 Tablet contains a substance called Naproxen. It belongs to a group of medicines called non steroidal anti-inflammatory agents (NSAIDs) which reduces fever and pain.

## Before you use Sunprox 550 Tablet

### - When you must not use it

Do not use Sunprox 550 Tablet:

- If you have active peptic ulceration
- If you are allergic to Naproxen, Aspirin, other NSAIDs or other ingredients of Sunprox 550 Tablet listed at the end of this leaflet.
- If you have had asthma, rhinitis (Inflammation of the nasal mucous membrane), urticaria (itching or hives), nasal polyps and the symptoms become worse caused by Aspirin or NSAIDs.

### - Before you start to use it

You should check with your doctor:-

- if you have heart problem or stroke
- if you have hypertension (high blood pressure)

- Naproxen may cause severe skin reactions, 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 reactions occur, stop use and seek medical assistance right away
- If you have kidney or liver problem
- If you are chronic alcoholic
- If you are elderly
- If you have or have had ulceration, bleeding and perforation of the stomach or intestinal
- If you are suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).
- If you have blood disorder
- Please consult your doctor before start to use Sunprox 550 Tablet 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 Sunprox 550 Tablet against the benefits they expect it will have for you.

### - Taking Other Medicines

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

Some medicines when taken with Sunprox 550 Tablet may interfere with each other. These include:

- Anticoagulant/thrombolytic agents (blood thinning agents)
- Probenecid, as an adjunct therapy in antibiotics or for gout
- Methotrexate, a medicine used to treat rheumatoid arthritis, as well as some types of cancer.
- Prednisolone, anti-inflammatory agent.
- Furosemide, water pills
- Salicylate, medicine to relieve pain
- Lithium, for depression
- Quinolone, medicines to treat the infection
- Hyhantoin, medicines for fit
- sulfonamides, for infection
- sulfonylureas, for diabetes
- Beta-blocker, for high blood pressure

## How to use Sunprox 550 Tablet

### - How much to use

Oral administration.

In rheumatic disorder, the usual initial dose of naproxen sodium is 275mg twice daily, adjusted to 1100 mg daily in 2

divided doses. Therefore it is not recommended for children under 16 years. In acute gout, an initial dose of 825mg followed by 275mg every 8 hours has been suggested. In dysmenorrhea, 550mg may be given initially followed by 275mg every 6 to 8 hours if needed. Total daily dose should not exceed 1.375g of naproxen sodium. Your doctor might prescribe to you a higher dosage of Sunprox 550 Tablet up to 1.65g per day if indicated. 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.

### - When to use it

It should be given with food.

### - How long to use it

It is important to take Sunprox 550 Tablet as long as your doctor prescribes

### - If you forget to use it

Do not take extra tablet to make up for a missed dose. Just take your next dose at usual the time

### - 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 tablets may cause mild nausea, indigestion, drowsiness, heartburn or vomiting.

## While you are using it

### - Things you must do

Take Sunprox 550 Tablet exactly the way as prescribed.

### - Things you must not do

Do not share your medicine with others even if they have the same diagnosis as you.

### - Things to be careful of

Be careful driving or operating machinery until you know how Sunprox 550 Tablet affects you. If you experience any side effects, consult your doctor or pharmacist for advise

## Side Effects

Like all medicines, Sunprox 550 Tablet can cause side effects, although not everybody gets them. Adverse reactions to naproxen mainly involve the Gastro-Intestinal (GI) tract. Constipation, heartburn, abdominal pain and nausea occurring in approximately 3-9% of patients whom taking this medicine. Symptoms such as diarrhea, vomiting, anorexia and abdominal bloating may occur. Naproxen may reactivate latent peptic ulcer (inflammatory of bowel disease) and cause peptic ulcers (gastric) in patients with no previous history of ulcers, bleeding and perforation of ulcers may occur, occasionally causing fatalities. Inability to concentrate, mental depression, nervousness, irritability fatigue, malaise, insomnia, sleep disorders and dream abnormalities may also occur. Skin itchy or rashes and discoloration of the skin caused by bruising may also occur. Hearing and visual disturbances, blood disorder such as thrombocytopenia, leukocytopenia may also happen during administration of naproxen.

If you encounter any other side effects not in this list, please inform your doctor or Pharmacist as well.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers→Reporting).

## Storage and Disposal of Sunprox 550 Tablet

### - Storage

Store at below 25°C. Protect from light.

### - 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

Oval, convex, blue, film-coated tablet with single score on one side only.

### - Ingredients

- Active Ingredients
- Naproxen sodium

### - Inactive Ingredients

- Microcrystalline Cellulose
- Corn Starch
- Sodium Starch Glycolate
- Sodium Lauryl Sulphate
- Magnesium Stearate
- Povidone K30 (PVP K30)
- Isopropyl Alcohol
- Hydroxypropyl Methylcellulose
- Deionised Water
- Polyethylene Glycol (PEG 6000)
- Titanium dioxide
- Calcium Carbonate Light
- Talcum
- Lake Blue No. 2 (30-36%)
- Hydroxypropyl Methylcellulose

### - MAL number

MAL19992402AZ

### **Manufacturer**

Sunward Pharmaceutical Sdn. Bhd.  
9,11 & 17 Jalan Kempas 4,  
Taman Perindustrian Tampoi Indah,  
81200 Johor Bahru, Johor, Malaysia.

### **Product Registration Holder**

Sunward Pharmaceutical Sdn. Bhd.  
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