# **SELADIN TABLET**

Naproxen (250mg, 500mg)

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## What SELADIN TABLET is used for

SELADIN TABLET is used for the relief of pain and inflammation in rheumatic disorder (inflammatory joint disease), acute gout and other musculoskeletal disorders.

#### How SELADIN TABLET works

SELADIN TABLET consists of active substance Naproxen, which belongs to the group of medicines called Non-Steroidal Antiinflammatory Drugs (NSAIDs). These medicine work by reduce inflammation, pain and fever.

## Before you use SELADIN TABLET

-When you must not use it

Do not take SELADIN TABLET if:

- you have hypersensitivity or allergic to Naproxen, aspirin or other NSAIDs. Some of the symptoms of allergic reaction may include skin rash, itchiness, shortness of breath, and swelling of the face, lips or tongue.
- you have or have had ulceration of the stomach
- you have severe kidney disease

## -Before you start to use it

Tell your doctor if you have or have had the following conditions:

- bleeding disorder
- heart failure or heart disease
- ulceration, bleeding or perforation of the stomach or intestinal
- elderly
- smoking or alcoholism
- stroke
- high blood pressure
- fluid retention or oedema
- suffering from dyspepsia (discomfort at the epigastric region due to digestion problem)

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.

## Pregnancy and lactation

Please consult your doctor before start to use SELADIN 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 SELADIN 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 SELADIN TABLET may interfere with each other. These include:

- Probenecid, medicine for gout
- Sulfonylurea, medicines for diabetes
- Hydantoin, medicine for fits
- Antihypertensives, medicines for high blood pressure
- Coumarin anti-coagulant, medicine for blood thinning
- Lithium, medicine for depression
- Methotrexate, a medicine used to treat rheumatoid arthritis, as well as some types of cancer

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

## **How to use SELADIN TABLET**

# -How much to use

In rheumatic disorders, the usual dose is 250mg twice daily, adjusted to 0.5g to 1g daily in 2 divided doses.

A dose of 10mg/kg/day in 2 divided doses has been used in children over 5 years with juvenile rheumatoid arthritis.

In acute gout, initial dose is 750mg followed by 250mg every 8 hours. In acute musculoskeletal disorders, 500mg initially, then 250mg every 6-8 hours as required.

After assessing the risk/ benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

## -When to use it

Use as directed by your doctor or pharmacist.

## -How long to use it

Please refer to doctor or pharmacist.

## -If you forget to use it

If you miss a dose of SELADIN TABLET take it as soon as possible. If it is approaching time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

## -If you use it 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.

## While you are using it

# -Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking SELADIN 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 take any new medicines without consulting your doctor.

Do not give this medicine to anyone else, even if they have the same symptoms or condition as you.

# -Things to be careful of

Driving and operating machinery
Be careful driving or operating machinery
until you know how SELADIN TABLET
affects you.

#### Side effects

Gastrointestinal: The most frequent complaints are related to stomach and intestinal tract such constipation, heartburn, abdominal pain, nausea, dyspepsia (indigestion), diarrhea, stomatitis (stomach ulcer).

Central nervous system: Headache, dizziness, drowsiness, lightheadedness, vertigo (spinning sensation).

Dermatologic: Itching (pruritus), skin eruptions, ecchymoses (bruises), sweating, purpura.

Special senses: Tinnitus (ringing in the ear), hearing and visual disturbances.

Cardiovascular: Edema, dyspnea (shortness of breath), and palpitations (feeling offast or irregular heart beat).

Hematology: Blood disorders and occasional bleeding and ulceration.

General: Thirst

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may 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 SELADIN TABLET

-Storage

Keep in airtight container. Store below 30°C, protect from light and moisture.

## -Disposal

If your doctor or pharmacist tells you to stop using SELADIN TABLET or the batch has passed the expiry date, ask your doctor or pharmacist what to do with any that is left over.

#### **Product description**

-What it looks like

SELADIN TABLET 250MG:

A slight yellow color tablet, one side impressed with a score.

## SELADIN TABLET 500MG:

A slight yellow color tablet, one side impressed with a score, the other side with a "YS" mark.

# -Ingredients

- -Active ingredient
- Naproxen
- -Inactive ingredient

Sodium Starch Glycolate

Talc

Magnesium Stearate

Iron Oxide Yellow

Magnesium Aluminometasilicate

Isopropyl Alcohol

Iron Oxide Red

Hydroxypropyl Cellulose

## -MAL number

SELADIN TABLET 250MG: MAL19988495AZ

SELADIN TABLET 500MG:

MAL19988494AZ

#### Manufacturer

Y.S.P. Industries (M) Sdn. Bhd. Lot 3, 5 & 7, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor Darul Ehsan, Malaysia.

## **Product Registration Holder**

Y.S.P. Industries (M) Sdn. Bhd. Lot 3, 5 & 7, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor Darul Ehsan, Malaysia.

#### Date of revision

24/02/2016

## **Serial Number**

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