NAPROXEN SODIUM

SKELAN®

220 mg FILM-COATED TABLET

Non-steroidal Anti-inflammatory Drug / Analgesic / Antipyretic

FORMULATION
Each film-coated tablet contains:
Naproxen (as Sodium).....220 mg

PRODUCT DESCRIPTION
Naproxen Sodium is a powder blue, elliptical shaped, film-coated tablet, plain on both sides.

WHAT IS IN THE MEDICINE?
This product contains Naproxen Sodium which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (also known as NSAIDs). Like other NSAIDs, Naproxen Sodium works by changing the body's chemical response to pain, swelling and fever resulting in relief of symptoms of inflammation (e.g., swelling, redness) and relief of pain and/or fever.

STRENGTH OF THE MEDICINE
See Formulation.

WHAT IS THE MEDICINE USED FOR?
- For the relief of headache;
- For the relief of toothache, muscular aches, minor arthritis pain, backache, minor aches and pains associated with the common cold, and pain of menstrual cramps (dysmenorrhea);
- For fever reduction.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Like other NSAIDs, the lowest effective dose of naproxen sodium should be used for the shortest possible time. This medicine is given orally (by mouth). Drink a full glass of water with each dose.
Adults and Children 12 years and older: 1 tablet every 8 to 12 hours as needed, or, as directed by a doctor.
- Do not exceed 2 tablets in any 8 to 12-hour period.
- Do not exceed 3 tablets in a 24-hour period.

Adults over 65 years: 1 tablet every 12 hours, or, as directed by a doctor.
- Do not take more than 1 tablet every 12 hours unless directed by a doctor.

Children under 12 years old: Consult a doctor before use.
Do not take more than directed.
Do not take longer than 10 days, unless directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
Do not take this medicine:
- If you are allergic to naproxen, aspirin, and other NSAIDs
- If you ever had asthma, rhinitis, or nasal polyps after taking aspirin or other NSAID medicine. Aspirin-sensitive patients should not take naproxen as reactions have the potential of causing death.
- If you have advanced kidney disease
- If you are pregnant or breastfeeding

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you missed a dose, take the next dose if still needed for pain and/or fever or inflammation and the subsequent dose every 8 to 12 hours thereafter.
Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?
Keep the product out of sight and reach of children.
Do not store above 30°C

SIGNS AND SYMPTOMS OF OVERDOSAGE
Symptoms of Naproxen overdosage may include lethargy (fatigue), dizziness, drowsiness, epigastric pain, abdominal discomfort, heartburn, indigestion, nausea, vomiting, transient alterations in liver function, hypoprothrombinemia, renal dysfunction, metabolic acidosis, apnea (brief pauses in breathing pattern) and disorientation. Gastrointestinal bleeding, hypertension, acute renal failure, respiratory failure, and coma may also occur. Anaphylactoid reactions (whole-body allergic reaction) may also occur following an overdose.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE
If you have taken more than the recommended dosage, consult a doctor or contact a Poison Control Center right away.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?
- **Allergy Alert:**

Naproxen Sodium may cause a severe allergic reaction which may include:
- Hives (elevated, whitish or reddish patches on the skin with severe itching or pricking sensations);
- Shock (anaphylactic) (a hypersensitivity reaction resulting in generalized skin lesions and itchiness, followed by low blood pressure and often accompanied by difficulty of breathing);
- Facial swelling
- Asthma (wheezing)

- If an allergic reaction occurs, stop use and seek medical help right away.

- **Stomach Bleeding Warning:**

This product contains an NSAID, which may cause severe stomach bleeding.
The chance is higher if you:
- Are age 60 years or older
- Have had stomach ulcers or bleeding problems
- Take a blood thinning (anticoagulant) or steroid medicine
- Take other medicines containing prescription or non-prescription NSAIDs (aspirin, ibuprofen or others)
- Have 3 or more alcoholic drinks everyday while using this product
- Take more or for a longer time than directed

- If stomach upset occurs, take this medicine with food or milk.
- When using this product the risk of heart attack or stroke may increase if you use more than directed or for longer than directed.
- Do not use after the expiry date on the label.

UNDESIRABLE EFFECTS
Naproxen can cause stomach ulcers that bleed. The chance of this serious problem increases the longer you take Naproxen and with higher doses.

The most commonly reported undesirable effects experienced with Naproxen Sodium 220 mg include headache, nausea, somnolence, dizziness, vomiting and dyspepsia.

Other undesirable effects which may be associated with Naproxen include:

Allergic reactions: Naproxen can cause serious allergic reactions such as asthma-like symptoms (problems in breathing, swallowing and wheezing) and rash.

Fluid retention: Naproxen can cause fluid retention (holding of water in your body) and swelling. Fluid retention can be a serious problem if you have high blood pressure or heart failure.

Liver damage: Stop taking Naproxen and tell your doctor right away if you have nausea, vomiting, tiredness, loss of appetite, itching, yellow coloring of skin or eyes, flu-like symptoms, and dark urine.

Kidney problems: Naproxen can cause serious kidney problems, including sudden kidney failure or worsening of kidney problems that you already have.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
- Cholestyramine, antacids and sucralfate may delay the absorption of Naproxen.

- Aspirin, phenylbutazone, indomethacin, salicylates, and other NSAIDs (e.g., mefenamic acid, ibuprofen, diclofenac, ketoprofen) may increase the risk of stomach and intestinal bleeding in patients receiving Naproxen.

- Aspirin and other highly protein-bound drugs such as sulfonylureas (e.g., glibenclamide, gliclazide, glipizide), hydantoins (e.g., phenytoin), sulphonamides (e.g., sulfamethoxazole) may affect naproxen concentration in the blood. Consult a doctor when taking these medications with Naproxen since dosage adjustment may be necessary.

- When taken with blood thinning (anticoagulant) medicines (e.g., warfarin, dicumarol) or together with thrombolytic agents (e.g., streptokinase), Naproxen may cause stomach and intestinal bleeding.

- Naproxen increases the amount of lithium in the blood (increased risk of toxicity) probably by reducing excretion of lithium.

- Naproxen may reduce the antihypertensive effect of ACE inhibitors (e.g., captopril, enalapril, ramipril, imidapril, fosinopril, lisinopril) and β-blockers (e.g., propranolol, metoprolol, atenolol, carvedilol).

- Naproxen may reduce the effect of diuretics such as furosemide and thiazide.

- When taken with probenecid, naproxen's plasma levels and half-life may be increased.

- Naproxen may enhance methotrexate toxicity.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
Ask a doctor before use if you are:
- Having problems or serious side effects from taking pain relievers or fever reducers;
- Taking any other product that contains naproxen;
- Taking any other medicine;
- Under a doctor's care for any serious condition.

Ask a doctor before use if:
- Stomach bleeding warning applies to you;
- You have a history of stomach problems, such as heartburn;
- You have or had angina (chest pain), heart attack, or blocked artery in your heart;
- You have high blood pressure, heart disease, liver cirrhosis, or kidney disease;
- You have asthma;
- You are taking a medicine to help reduce the amount of water in the body (diuretic).

Stop use and ask a doctor if:
- You experience any of the following signs of stomach bleeding:
  - Feel faint
  - Vomit blood
  - Have bloody or black stools
  - Have stomach pain that does not get better

- Pain gets worse or lasts more than 10 days
- Fever gets worse or lasts more than 3 days
- You have difficulty swallowing
- It feels like the tablet is stuck in your throat
- Redness and swelling is present in the painful area
- Any new symptoms appear

If you are pregnant or breastfeeding, ask a doctor before use. It is especially important not to use ibuprofen during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY: Box of 100's and Polycard x 4's (in Flex foil x 4's)
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