ROXONIN®

Analgesic, anti-inflammatory and anti-pyretic agent.

COMPOSITION

ROXONIN® Tablets: Each tablet contains 68.1 mg of loxoprofen sodium (JP) (60 mg as anhydrous).

INDICATIONS

Anti-inflammatory and analgesic action in the following diseases and symptoms: Rheumatoid arthritis, osteoarthritis, low back pain, scapulohumeral periarthritis and neck-shoulder-arm syndrome.
Analgesic and anti-inflammatory action after operation, trauma or tooth extraction.
Antipyretic and analgesic action in the following diseases: Acute upper respiratory tract inflammation. Acute upper respiratory tract inflammation accompanied by acute bronchitis.

DOSAGE AND ADMINISTRATION

Usually for adults, administer orally one tablet 60mg of loxoprofen sodium three times a day. For a single administration, 1-2 tablets are orally given. The dosage may be adjusted depending on the patient's age and symptoms.

PRECAUTIONS

Careful Administration (This product should be administered with caution in the following patients)

- Patients with a history of peptic ulcer (A relapse of ulcer may occur.)
- Patients with peptic ulcer caused by a long-term administration of nonsteroidal anti-inflammatory drugs.
- Patients with hematological disorder or a history thereof (Adverse reactions including hemolytic anemia are apt to occur).
- Patients with hepatic disorder or a history thereof (Hepatic disorder may be relapsed or exacerbated).
- Patients with renal disorder or a history thereof (Adverse reactions such as edema, proteinuria and increase in serum creatinine may occur).
- Patients with cardiac dysfunction (See 'Contraindications').
- Patients with a history of hypersensitivity.
- Patients with bronchial asthma (The pathophysiologic condition may be exacerbated).

CONTRAINDICATIONS

(This product is contraindicated in the following patients.)

1 - Patients with peptic ulcer (Since prostaglandin biosynthesis inhibition decreases blood flow in the stomach, peptic ulcer may be exacerbated). (If you use ROXONIN® for patients with peptic ulcer see “Careful Administration”).
2 - Patients with serious hematological disorder (This product may cause platelet function disorder, leading to aggravation of hematological disorder).
3 - Patients with serious hepatic disorder (Since occurrence of hepatic disorder has been reported as an adverse reaction, this product may worsen hepatic disorder).
4 - Patients with serious renal disorder (Adverse reaction such as acute renal failure and nephrotic syndrome may occur).
5 - Patients with serious cardiac function failure (Since prostaglandin biosynthesis inhibition in the kidney causes edema and increase in circulating body fluid, the workload of the heart increases; aggravation of the symptom may occur).
6 - Patients with hypersensitivity to any ingredients of this product.
7 - Patients with aspirin asthma (induction of an asthmatic attack by nonsteroidal anti-inflammatory drugs, etc.) or patients with a history thereof (Aspirin asthmatic attack may be induced).
8 - Women during late pregnancy (See “Use during Pregnancy, Delivery or Lactation”).

DRUG INTERACTIONS

Precaution for coadministration ROXONIN® should be administered with care when coadministered with the following drugs:
Coumarin-type anticoagulants (e.g., warfarin) - Sulfonyl urea hypoglycemic drugs (e.g., tolbutamide). New quinolone antibacterial drugs (e.g., enoxacin) - Lithium preparations(lithium carbonate) Benzothiadiazine diuretic drugs (e.g., hydroflumethiazide and hydrochlorothiazide).

Adverse Reactions

3% of patients of ROXONIN® were reported to have experienced adverse reactions. The primary reactions were digestive symptoms (stomach/abdominal discomfort, stomachache, nausea/vomiting, anorexia, etc.), edema/swelling, rash/urticaria, sleepiness etc.

Use in the Elderly

In elderly patients, adverse drug reactions are apt to occur. Therefore, careful administration, such as starting with a low dose, is needed under observation of patient’s condition.

Use during Pregnancy, Delivery or Lactation

The product should only be used in pregnant women and women suspected of being pregnant, provided that the expected therapeutic benefits are evaluated to outweigh the possible risk of treatment. (The safety of the product in pregnant women has not been established).
This drug should not be administered to women during late pregnancy.
Adiminstration to nursing mothers should be avoided. When it is indispensable, breast feeding should be discontinued.

PHARMACOKINETICS

Absorption and metabolism

ROXONIN® is rapidly absorbed and appeared not only as loxoprofen (unchanged form) but also as Trans-OH form (active metabolite) in the circula-ting blood. The blood level of ROXONIN® and its metabolites reached peaks about 30 minutes and about 50 minutes after administration, respectively, and their elimination half-lives were both about 1 hour 15 minutes.

Excretion

Urinary excretion of ROXONIN® is rapid, and most of the drug administered is excreted in the unchanged form or as the glucuronide of the active form. Approximately 50% of the dose is excreted in the urine within 8 hours after administration.

PHARMACOLOGY

Loxoprofen sodium has excellent analgesic, anti-inflammatory and antipyretic effects, and its analgesic effect is especially powerful. Loxoprofen sodium is a prodrug which produces effects after being absorbed from the gastrointestinal tract followed by conversion to an active metabolite.

1. Analgesic action

Its analgesic effect is 10 to 20 times more potent than those of reference drugs such as ketoprofen, naproxen and indomethacin.

2. Anti-inflammtory action

The anti-inflammatory action of loxoprofen sodium against acute and chronic inflammations is nearly equal to those of ketoprofen and naproxen.

3. Antipyretic action

Loxoprofen sodium shows an anti-pyretic effect on fever nearly as potent as those of ketoprofen and naproxen and about three times more potent than of indomethacin.

Mechanism of action

The mechanism of action of loxoprofen sodium is due to inhibition of prostaglandin biosynthesis and its site of action is cyclooxygenase. After oral administration, loxoprofen sodium is absorbed from the digestive tract in the unchanged form, which causes just weak irritation of the gastric mucosa, and is then rapidly converted to an active metabolite which potently inhibits prostaglandin biosynthesis.

Storage Conditons

The product should be stored below 30°C.

Roxonin® tablets

Boxes of 20 tablets.

Expiration date

The product should be used before the expiration date specified on the outer package .

Manufactured by :
SAJA Pharmaceuticals Co., Ltd.
Saudi Arabian Japanese Pharmaceutical Company
Under License from
Daiichi Sankyo Co. Ltd.
Tokyo - Japan

THIS IS A MEDICAMENT

- A drug is a product which acts on your health and its consumption could be dangerous when you do not follow the instructions.
- Follow strictly the doctor's prescriptions, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist know the medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep out of the reach of children.

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