ROXONIN® 60mg Tablets

Loxoprofen Sodium

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. WHAT ROXONIN® IS AND WHAT IT IS USED FOR

ROXONIN belongs to a group of medicines called Non-Steroidal Anti- Inflammatory drugs (NSAIDs).
ROXONIN has excellent analgesic, anti-inflammatory and antipyretic properties, with particularly potent pain-relieving activity. This drug is a prodrug which, after being absorbed from the gut, is biotransformed into an active metabolite to exert its actions.
ROXONIN are used for;
1) Relief of inflammation and pain in the following disorders and symptoms: Rheumatoid arthritis, osteoarthritis, lower back pain, periarthritis of the shoulder, and shoulder-arm-neck syndrome, toothache.
2) Relief of postoperative, post-traumatic or post-exodontial pain and inflammation
3) Antipyresis and relief of pain in the following disorder: Acute upper respiratory, tract inflammation, (including acute upper. airway inflammation, accompanying acute bronchitis)

2.BEFORE YOU TAKE ROXONIN®

Do not take ROXONIN, if you have;
- Peptic ulcers [Peptic ulcers may be aggravated due to reduced gastric blood flow resulting from inhibition of prostaglandin biosynthesis.]
- Severe blood disorders [Platelet dysfunction may occur and the abnormality may be worsened.]
- Severe hepatic functions disorders [Hepatic function disorders have been reported with the use of ROXONIN, and the patient's hepatic function disorder may be aggravated.]
- Severe renal impairment [Adverse reactions such as acute kidney injury, nephrotic syndrome, etc. have been reported with the use of ROXONIN.]
- Severe cardiac function failure [Cardiac symptoms may be exacerbated because inhibition of prostaglandin biosynthesis in the kidneys may cause edema and an increase in circulating body fluid volume, with a consequent increase in cardiac work.]
- A history of hypersensitivity to any ingredients of ROXONIN .
- Or with A history of aspirin-induced asthma (induction of asthmatic attack with non steroidal anti-inflammatory-analgesics, etc.) [May induce an aspirin-induced asthmatic attack.]
- Pregnancy in late stage [See "Use during Pregnancy, and breast feeding"]

Take special care with ROXONIN

Before taking ROXONIN, tell your doctor if you
- Have a history of peptic ulcers [since the use of ROXONIN may cause recurrence of ulceration.]
- Have Peptic ulcer associated with chronic use of nonsteroidal anti-inflammatory-analgesic agents whose clinical condition requires long-term administration of ROXONIN and if you are currently on misoprostol therapy [ROXONIN must be administered with care while your doctor should closely monitoring your clinical condition if you are receiving this drug continuously, because peptic ulcers may be refractory to treatment with misoprostol, which is indicated for nonsteroidal antiinflammatory- analgesic drug-induced peptic ulceration.]
- Have Blood disorders or with a history of blood disorders [since adverse reactions such as hemolytic anemia are prone to occur.]
- Have Hepatic function disorders or with a history of hepatic function disorders [because exacerbation or recurrence of the hepatic function disorders have been reported with the use of ROXONIN.]
- Have Renal impairment or with a history of renal impairment [since adverse reactions such as edema, proteinuria, serum creatinine elevation or hyperkalemia have been reported with the use of ROXONIN.]
- Have Cardiac dysfunction [See "Don't take ROXONIN"]
- Have A history of hypersensitivity
- Have Bronchial asthma [as the disease state may be exacerbated.]
- Have Colitis ulcerative [as the disease state may be exacerbated.]
- Have Crohn's disease [as the disease state may be exacerbated.]
- Are Elderly subjects [See "Use in the Elderly".]

NSAID Relevant Risks
- The risk of heart attack or stroke can occur as early as the first weeks of using an NSAID. The risk may increase with longer use of the NSAID.
- The risk appears greater at higher doses.
- The risk for heart attack or stroke is similar for all NSAIDs.
- NSAIDs can increase the risk of heart attack or stroke in patients with or without heart disease or risk factors for heart disease. A large number of studies support this finding, with varying estimates of how much the risk is increased, depending on the drugs and the doses studied.
- In general, patients with heart disease or risk factors for it have a greater likelihood of heart attack or stroke following NSAID use than patients without these risk factors because they have a higher risk at baseline.
- Patients treated with NSAIDs following a first heart attack were more likely to die in the first year after the heart attack compared to patients who were not treated with NSAIDs after their first heart attack.
- There is an increased risk of heart failure with NSAID use.

Taking other medicines

Some medicines can affect the way other medicines work. **Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines,** including medicines obtained without a prescription:
- Aspirin (acetylsalicylic acid) or other NSAIDs (e.g. ibuprofen)
- Medicines used to treat osteoarthritis or rheumatoid arthritis known as cyclo-oxygenase2- (COX2-) inhibitors It is recommended to avoid the concomitant use of other anti-inflammatory- analgesic agents with ROXONIN
- Diuretics (used to treat excess fluid in the body)
- Lithium (used to treat some types of depression)
- Warfarin or other oral anticoagulants (blood-thinning agents that reduce blood clotting)
- Medicines used to control your blood sugar (oral hypoglycaemics for diabetes)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia)
- Quinolone antibiotics (used to treat some infections)
- Factor Xa inhibitors: the risk of bleeding may be increased

Pregnancy and breast-feeding

Pregnancy

You should ask your doctor if you are or are possibly pregnant before taking this drug. ROXONIN should be administered only when the anticipated therapeutic benefits are considered to outweigh any potential risk. [The safety of this ROXONIN in these populations has not been established.]
It can cause kidney and heart problems in your unborn baby. It may affect your and your's baby tendency to bleed and cause labour to be later or longer than expected.
If taken for more than a few days from 20 weeks of pregnancy onward, Loxoprofen can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (Oligohydramnios) or narrowing of blood vessels (Ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.
You should not take this medicine if you are in the late stages of pregnancy.

Breast-feeding

You should not take this medicine if you are breastfeeding. If administration of this drug is judged to be essential, nursing should be discontinued.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Some patients may experience side effects such as dizziness, sleepiness. To be safe, you should be careful when driving and using machine.
If you suffer from these effects, you should not drive or perform other activities that require you to be alert and ask your doctor or pharmacist for advice.

3.HOW TO TAKE ROXONIN®

Dosage

Always take ROXONIN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Take one tablet two or three times a day, or as directed by your doctor.
The recommended daily dose of ROXONIN is twice daily administration, and the total daily dose should not exceed 180 mg/day.

Methods and routes of administration

ROXONIN should be swallowed whole with a drink of water (not chewed), taken during or after mealtimes.
Use of ROXONIN on an empty stomach should be avoided.
You should remove each tablet from the PTP blister package before taking the drug. [It has been reported that accidental ingestion of the blister package can lead to esophageal mucosal injury and subsequent perforation caused by the pointed corner of the package, resulting in serious complications such as mediastinitis.

Children

ROXONIN are not recommended for use in children.

Elderly patients

ROXONIN should be used with caution, e.g. starting at a low dose as adverse reactions are likely to occur in elderly patients. Your doctor may want to monitor you more closely. (See "Before you take ROXONIN ").

If you have kidney or liver problems

Your doctor will decide if this medicine is suitable for you and the correct dose for you to take.

If you take more ROXONIN than you should

You should not take more tablets than your doctor tells you to. If you or someone else has taken too much ROXONIN contact your doctor, pharmacist or hospital as soon as possible, Please carry with you the product leaflet or remaining tablets for better identification of the doctor.

If you forget to take ROXONIN

If you forget to take a tablet, take it as soon as you remember. Do not take a double dose to make up for forgotten doses.

If you stop taking ROXONIN

Your doctor has told you how long you should take ROXONIN. Do not stop taking ROXONIN unless your doctor tells you to. If you have any questions on the use of this product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ROXONIN can cause side effects, although not everybody gets them. If you are worried about side effects, ask your doctor. It is important that you know what can happen, so that you can take action if ROXONIN does have a side effect
The following side effects have been observed during treatment with ROXONIN:
The major adverse reactions reported were gastrointestinal symptoms (Stomach discomfort, abdominal pain, nausea and/or vomiting, anorexia, etc.: %2.25); edema (%0.59); rash, urticaria, etc. (%0.21); and sleepiness (%0.10).

(1)Clinically significant adverse reactions (incidence unknown)

If any of the following happen, stop taking ROXONIN and tell your doctor immediately
- Shock and anaphylactoid symptoms: (decreased blood pressure, urticaria, edema of the larynx, dyspnea, etc.)
- Hemolytic anemia, leukopenia, and thrombocytopenia
- Agranulocytosis
- Oculomucocutaneous syndrome and toxic epidermal necrolysis.
- Erythema multiforme
- Acute generalized exanthematous pustulosis (frequency unknown)
- Acute kidney injury, nephrotic syndrome and interstitial nephritis.
- Cardiac failure congestive.
- Interstitial pneumonia with manifestations of fever, cough, dyspnea.
- Gastrointestinal bleeding: Serious peptic ulceration or gastrointestinal bleeding from the small intestine and/or large intestine, e.g., hematemesis, melena and hematochezia, and consequent shock.
- Gastrointestinal perforation
- Hepatic function disorders including jaundice, increased serum levels of AST (GOT), ALT (GPT) and /or fulminant hepatitis.
- Asthmatic attack.
- Aseptic meningitis including fever, headache, nausea and vomiting, nuchal rigidity, clouding of consciousness (in particular, the adverse event is likely to occur in the patients with systemic lupus erytgematosus or mixed connective tissue disease).
- Stenosis and/or obstruction of the small intestine and/or large intestine: Stenosis and or obstruction with ulcer of the small intestine and or large intestine have been reported with the use of loxoprofen. Patients should be carefully observed during treatment.
- Rhabdomyolysis

(2) Clinically significant adverse reactions reported in association with the use of other non steroidal anti-inflammatory-analgesic drugs

Aplastic anemia: Aplastic anemia has been reported in association with the use of other non-steroidal anti-inflammatory-analgesic drugs.

(3) Other adverse reactions

Adverse Reactions	Frequency of Adverse Reactions			
	0.1 to <1.0%	0.05to <0.1%	<0.05%	Incidence unknown
Hypersensitivity *	Rash	Pruritus	Urticaria	Fever
Gastrointestinal	Abdominal pain Stomach discomfort Anorexia Nausea and/ or vomiting Diarrhea	Peptic ulcer* Constipation Heartburn Stomatitis	Dyspepsia	Thirst Abdominal Distension
Cardiovascular			Palpitations	Blood pressure increased
Psychone-urologic	Sleepiness		Headache	Numbness Dizziness
Hematologic			Anemia Leukopenia Eosinophilia	Thrombocytopenia
Hepatic	Increased AST (GOT) increased ALT (GPT)		Increased ALP	
Urinary				Hematuria Proteinuria
Others	Edema		Facial-warmth	Chest pain Malaise

* Discontinue administration.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ROXONIN®

Keep out of the reach and sight of children.
Store below "30C.
Do not use your tablets after the expiry date stated on the carton or label. .
Medicinal 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.

6. FURTHER INFORMATION

What ROXONIN contains
- The active substance is Loxoprofen sodium hydrate (JP) 68.1 mg (60 mg as anhydride)
- The other ingredients Low Substituted Hydroxypropylcellulose, Red Ferric Oxide, Lactose hydrate, Magnesium Stearate

What ROXONIN look like and contents of the pack

ROXONIN® is pale red tablet, Coded by (SJ 112) in one side.
Available in packs containing 20 and 40 tablets.

Marketing Authorisation Holder and Manufacturer

SAJA Pharmaceuticals
Saudi Arabian Japanese pharmaceutical company limited
Jeddah – Saudi Arabia
Under license from Daiichi Sankyo Co. Ltd.
Tokyo-Japan
For any information about ROXONIN, please contact:
Saudi Arabian Japanese pharmaceutical company limited
Jeddah – Saudi Arabia
P.O. Box: 42600, Jeddah 21551, KSA
Tel: + 966 12 606 6667
sajapharma.com
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-To report any side effect (s)

• Saudi Arabia :

- The National Pharmacovigilance Centre (NPC):
- SFDA Call Center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa

• Other GCC states /other countries

-Please contact the relevant competent authority.

This is a Medicament

– Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
– Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
– The doctor and the pharmacist are the experts in medicines, their 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 all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists