

ROFENAC®

Antirheumatic, anti-inflammatory, analgesic

Patient Information Leaflet (PIL)
Rofenac
(Diclofenac sodium)
Rofenac® 25 mg, 50 mg, 100 mg enteric coated Tablets

Read all of this leaflet carefully before you start taking this medicine. Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be 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 or pharmacist.

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1. WHAT ROFENAC ARE AND WHAT THEY ARE USED FOR

Diclofenac sodium, the active ingredient in Rofenac, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

- Rofenac 100 mg tablets are specially formulated to release the diclofenac sodium slowly.
- Rofenac relieves pain, reduces swelling and eases inflammation in conditions affecting the joints, muscles and tendons including:
Rheumatoid arthritis, osteoarthritis, acute gout, ankylosing spondylitis
Backache, sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations and fractures
Tendonitis, tenosynovitis, bursitis.
- They are also used to treat pain and inflammation associated with dental and minor surgery.

2. BEFORE YOU TAKE ROFENAC

a. Do not take Rofenac if

- You think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Rofenac. (These are listed at the end of the leaflet.) Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, runny nose, skin rash or any other allergic type reaction

- You have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in feces or black, tarry feces)
- You have had stomach or bowel problems after you have taken other NSAIDs
- You have severe heart, kidney or liver failure
- You are more than six months pregnant (see Pregnancy and Lactation).

b. Take special care with Rofenac

- If you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- If you have kidney or liver problems, or are you elderly
- If you have a condition called porphyria
- If you suffer from any blood or bleeding disorder, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- If you have ever had asthma
- If you are breast-feeding
- If you have heart problems, or have you had a stroke, or do you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker)
- If you have Lupus (SLE) or any similar condition

Taking other medicines, herbal or dietary supplements

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics (water tablets).
- Lithium (used to treat some mental problems).
- Methotrexate (for some inflammatory diseases and some cancers).
- Ciclosporin or tacrolimus (used to treat some inflammatory diseases and after transplants).
- Quinolone antibiotics (for infections).
- Any other NSAID for example aspirin or ibuprofen or COX-2 (cyclo-oxygenase-2) inhibitor.
- Mifepristone (a medicine used to terminate pregnancy)
- Cardiac glycosides (for example digoxin), used to treat heart problems.
- Medicines known as SSRIs used to treat depression
- Oral steroids (an anti-inflammatory drug)
- Medicines used to treat heart conditions or high blood pressure, for example beta- blockers or ACE inhibitors.
- Sulfapyrazole (a medicine used to treat gout) or voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)

Always tell your doctor or pharmacist about all the medicines you are taking.

This means medicines you have bought yourself as well as medicines on prescription from your doctor.

e. Pregnancy and Lactation

- Are you pregnant or planning to become pregnant? Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy.

You should not take Rofenac during the last 3 months of pregnancy as it may affect the baby's circulation.

- Are you trying for a baby? Taking Rofenac may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

f. Driving and using machines

Very occasionally people have reported that Rofenac have made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

Other special warnings

- You should take the lowest dose of Rofenac for the shortest possible time, particularly if you are underweight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like Rofenac. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Because it is an anti-inflammatory medicine, Rofenac may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Rofenac.
- Rofenac tablets are not suitable for children

3. HOW TO TAKE ROFENAC

The doctor will tell you how many Rofenac to take and when to take them. Always follow his/her instructions carefully.

If you are not sure, ask your doctor or pharmacist. Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor.

Taking Rofenac with Food and drink

Take the tablets with or after food.

Swallow the tablets whole with a glass of water. Do not crush or chew them as this will affect them.

The usual doses are:

Adults

100-150 mg daily divided into two or three doses. The number of tablets which you take will depend on the strength the doctor has given you.

Elderly

Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor may also want to check closely that the Rofenac are not affecting your stomach.

These tablets are not suitable for children.

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

What if you forget to take a dose?

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, though, just take the next dose and forget about the one you missed. Do not double up on the next dose to make up for the one missed. Do not take more than 150 mg in 24 hours.

What if you take too many tablets?

If you, or anyone else, accidentally take too much, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

4. POSSIBLE SIDE EFFECTS

Rofenac are suitable for most people, but, like all medicines, they can sometimes cause side effects.

Some side effects can be serious

Stop taking Rofenac and tell your doctor straight away if you notice:

- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry feces
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering
- Wheezing or shortness of breath (bronchospasm)
- Swollen face, lips, hands or fingers
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

The side effects listed below have also been reported.

Common side effects (These may affect between 1 and 10 in every 100 patients):

- Stomach pain, heartburn, nausea, vomiting, diarrhea, indigestion, wind, loss of appetite
- Headache, dizziness, vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood.

Rare side effects (These may affect between 1 in every 1000 to 1 in every 10,000 patients):

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhea with blood in it or bleeding from the back passage
- Black, tarry faces or stools
- Drowsiness, tiredness
- Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness)
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis and jaundice.

Very rare side effects (These may affect less than 1 in every 10,000 patients):

Effects on the nervous system:

Tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, taste changes, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease). Effects on the heart, chest or blood:

Palpitations (fast or irregular heart beat), chest pain, hypertension (high blood pressure), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), heart disorders, including congestive heart failure or heart attack, blood disorders (including anaemia) and stroke.

Effects on the liver or kidneys:

Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.

Effects on skin or hair:

Serious skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight.

Hair loss.

Other side effects that have also been reported include:

Inflammation of the pancreas, impotence. Facial swelling, inflammation of the lining of the brain (meningitis), stroke, throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye.

Do not be alarmed by this list - most people take Rofenac without any problems.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

5. HOW TO STORE ROFENAC

Rofenac enteric coated tablets:

Store below 30°C

Keep out of the reach and sight of children.

Do not take Rofenac after the expiry date which is printed on the outside of the pack.

If your doctor tells you to stop taking the tablets, please take any unused tablets back to your pharmacist to be destroyed. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. FURTHER INFORMATION

a. What Rofenac contains

Each enteric coated tablet contains 25 mg or 50 mg or 100 mg diclofenac sodium.

- Rofenac enteric coated tablets also contain the inactive ingredients which are:

Excipients:

Lactose BP 200, Maize Starch, Methocel K-100M Premium, Povidone 30,

Colloidal Silicon Dioxide, Purified Talc, Magnesium Stearate, Avicel PH 102.

Coating Material:

Opadry Green OY-A-31064, Ammonia Solution, Hydroxypropyl Methylcellulose, Polyethylene Glycol MW 400, Polyethylene Glycol MW 6000, Titanium Dioxide, Magnesium Stearate, Polysorbate 80, Iron Oxide Red, Purified Talc, Ariabel Yellow 300,407.

Enteric Coating:

Eudragit L30D (30% Sol'n), Purified Talc, O-acetyl Triethylcitrate.

b. What Rofenac looks like and contents of the pack

Rofenac 25 mg enteric coated tablets: A white to off-white, round biconvex tablet, engraved with a crescent logo on one side and the other side with letters "SP" and number "137"

Rofenac 50 mg enteric coated tablets: A round biconvex light brown enteric-coated table; engraved with crescent logo on one side and the other side with letters "SP" and numbers "116"

Rofenac 100 mg enteric coated tablets: A round, pink, slightly, biconvex film-coated tablet engraved letters "SP" and number "118" on one side and the crescent logo on the other side.

Contents of pack:

Each Rofenac enteric coated tablets pack contains 30 enteric coated tablets

c. Marketing Authorization Holder and Manufacturer

SPIMACO

Al-Qassim Pharmaceutical Plant

Saudi Pharmaceutical Industries &

Medical Appliances Corporation

This leaflet was revised in July 2012.

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'ROFENAC' is a trade mark
34RF520

To report any side effect(s)

- National Pharmacovigilance Centre (NPC):
 - o Fax : +966-1-210-7398
 - o E-mail: npc.drug@sfd.gov.sa
 - o Website: www.sfd.gov.sa/npc

This is a medicament

- A 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 pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in 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 medicaments out of the reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists