Antirheumatic, Anti-inflammatory, Analgesic (Diclofenac sodium)

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 gel: For the local symptomatic relief of pain and inflammation of these conditions
- 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.

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).

Rofenac gel:
Rofenac gel should not be applied to damaged skin, whatever the lesion involved: exudative dermatitis, eczema, infected lesion, burn or wound.

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 Rofenac.
- 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 (cyclooxygenase-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.
• Sulfinpyrazone (a medicine used to treat gout) or voriconazole (a medicine used to treat fungal infections).
• Phenytoin (a medicine used to treat seizures)
• Colestipol/cholestryramine (used to lower cholesterol)

For Rofenac gel:
To date, no drug interactions during treatment with Rofenac gel have been reported but the theoretical risk of interactions listed above occurring should be borne in mind.
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 use Rofenac during the last 3 months of pregnancy as it may affect the baby’s circulation.
• Are you trying for a baby? using 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.

Breast-feeding:
Like other NSAIDs, diclofenac passes into breast milk in small amounts.
However, at the recommended therapeutic doses of Rofenac no effects on the suckling child are anticipated. Because of a lack of controlled studies in lactating women, the product should only be used during lactation under advice from a healthcare professional. Under this circumstance, Rofenac should not be applied on the breasts of nursing mothers, nor elsewhere on large areas of skin or for a prolonged period of time.

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. Although, Cutaneous application of topical diclofenac has no influence on the ability to drive and use machines.

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 using Rofenac.

3. How to use Rofenac
The doctor will tell you how many Rofenac to take and when to take it. Always follow his/her instructions carefully.
If you are not sure, ask your doctor or pharmacist. Keep taking your treatment 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
Use Rofenac gel after food.
Rofenac gel is to be applied to the painful area 3-4 times daily and rubbed in gently.
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.

What if you use too much Rofenac?
Due to the low systemic absorption of Rofenac, overdosage is extremely unlikely as a result of topical use. However, the skin should be rinsed with water.

There have been no clinical cases of ingestion of Rofenac inducing overdosage.
In the event of accidental ingestion (100 g Rofenac gel contain the equivalent of 3000 mg diclofenac sodium) resulting in significant systemic side effects, general therapeutic measures normally adopted to treat poisoning with nonsteroidal anti-inflammatories should be used.

If you, or anyone else, accidentally use 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 used.

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.

Rofenac gel:
The likelihood of systemic side effects occurring following the topical application of Rofenac is very small compared to the frequency of side effects with oral diclofenac.

Do not be alarmed by this list - most people use 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 gel:
Store below 30°C
Keep out of the reach and sight of children.
Do not use Rofenac after the expiry date which is printed on the outside of the pack.

If your doctor tells you to stop using Rofenac, please take any unused amount 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 tube of Rofenac gel contains 1% diclofenac sodium.
- Rofenac gel also contains the inactive ingredients which are:
  Excipients: Purified Water, Lutrol F 127 poloxamer 407, Benzyl Alcohol, Fresh Bouquet, Propylene Glycol

b. What Rofenac looks like and contents of the pack
Rofenac 1% Gel: a smooth, uniform, non-greasy clear gel with characteristic odor; dispersible in water.
Contents of pack:
Each Rofenac gel pack contains 1 tube with volume 50 gm. Or 100 gm.
This leaflet was revised in July 2012.