Ronac

Diclofenac Sodium Injection

Ronac Plus

Diclofenac Sodium &
Lidocaine Hydrochloride Injection

Presentation

Ronac IM Injection: Each ampoule contains 3 ml sterile solution of Diclofenac Sodium BP 75 mg for IM injection.

Ronac Plus IM Injection: Each ampoule contains 2 ml sterile solution of Diclofenac Sodium BP 75 mg and Lidocaine Hydrochloride BP 20 mg for IM injection.

Pharmacodynamic Properties

Diclofenac is a non-steroidal agent with marked analgesic/anti-inflammatory properties. The action is principally inhibition of prostaglandin synthesis. Diclofenac inhibits the synthesis of prostaglandin by inhibiting cyclooxygenase enzyme.

Lidocaine is the most widely used local anaesthetic drug. It acts more rapidly and is more stable than most other local anaesthetics, lidocaine impairs the generation and conduction of the nerve impulses by slowing depolarization.

Pharmacokinetic Properties

Absorption

Diclofenac is absorbed after all forms of administration. The plasma concentration of the agent is linearly proportional to the administered dose.

Peak plasma concentrations of diclofenac are achieved within half an hour following injection.

Distribution

Diclofenac binds 99.7 % to serum proteins mainly with albumin (99.4 %).

Diclofenac passes into the synovial fluid. Here maximum concentrations are measured 2 - 4 hours after maximal plasma values have been reached. The elimination half-life of the synovial fluid is 3 - 6 hours.

Metabolism

The metabolism of diclofenac occurs quickly and almost completely. It is extensively metabolized to a range of phenolic compounds. The metabolism occurs for a small part by glucuronidation of the unchanged molecule, but mainly a simple or multiple hydroxylation which leads to a formation of several phenolic metabolites (3-hydroxy-, 4-hydroxy-, 5-hydroxy-, 4,5-dihydroxy- and 3-hydroxy-4-methoxydiclofenac), which are then extensively conjugated to glucuronic acid.

Elimination

The terminal half life of Diclofenac in plasma is 1-2 hours. 60 % of the administered amount of diclofenac is renally eliminated as metabolites, less than 1 % of the active substance is eliminated in its unchanged form. The rest is excreted via the bile in metabolite forms.

The onset of anaesthesia of lidocaine HCl is more rapid and the duration of action is longer. A 1%-2% solution has a duration of action of about 1-2 hours. Binding of lidocaine to plasma proteins is variable and concentration dependent. Approximately 90% of a parenteral dose of lidocaine is rapidly metabolized in the liver. Less than 10% of a dose is excreted unchanged in the urine.

Indications

Ronac, Ronac Plus contains Diclofenac Sodium, which has got the following therapeutic uses:

❖ Rheumatoid Arthritis ❖ Osteoarthritis ❖ Low back pain & other acute musculoskeletal disorders such as periarthritis, sprains,strains tendonitis and dislocations. ❖ Renal colic ❖ Acute gout ❖ Acute trauma & fractures ❖ Post operative pain ❖ Juvenile chronic arthritis.

Ronac plus also contains Lidocaine, which acts as a local anaesthetic. Therefore, the possibility of pain at the injection site, which is most likely to occur after intramuscular injection of normal diclofenac, is minimized if this injection is used in the above indications.

Dosage and Administration

Ronac injection/Ronac Plus injection

Adults: One ampoule once (or in severe cases, twice) daily by intramuscular injection.

Renal colic: One ampoule once daily intramuscularly. A further ampoule may be administered after 30 minutes, if necessary. The recommended maximum daily dose of diclofenac is 150 mg. The recommended maximum daily dose of lidocaine is 200 mg.

Children: In juvenile chronic arthritis, 1-3 mg of diclofenac/kg body wt. daily in divided doses.

Elderly patients: In elderly or debilitated patients, the lowest effective dosage is recommended, commensurate with age and physical status.

Contraindications

Hypersensitivity to diclofenac or any of the excipients. NSAIDs should not be administered to patients with active or a history of recurrent peptic ulcer/ haemorrhage (two or more distinct episodes of proven ulceration or bleeding). Diclofenac should be given with precaution to the patients with asthma and bronchospasm, bleeding disorders, cardiovascular disease, peptic ulcer and renal failure.

Because of the presence of Lidocaine, it is also contraindicated for those patients who are hypersensitive to local anaesthetics of the amide type, although the incidence is very rare.

Side Effects

If serious side-effects occur, Diclofenac should be withdrawn.

Gastrointestinal: The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease and have been reported following administration.

Hypersensitivity: Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of a) non-specific allergic reactions and anaphylaxis b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea or c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema.

Cardiovascular: Oedema has been reported in association with NSAID treatment.

Drug Interactions

Increases plasma conc. of warfarin, lithium and methotrexate. May reduce effects of diuretics & ß blockers. May alter plasma conc. of sulfonylureas, It also potentiates the effect of other NSAIDS and glucocorticoids.

Use in Pregnancy and Lactation

It should not be prescribed during pregnancy, unless there are compelling reasons for doing so. Thise type of drugs are not recommended during the last trimester of pregnancy.

In the limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding.

Storage Condition

Store in a cool and dry place, away from light. Keep out of reach of children.

Commcial Pack

Ronac Injection: Each box contains 2 blister packs of 5 ampoules of 3 ml sterile solution.

Ronac Plus Injection: Each box contains 2 blister packs of 5 ampoules of 2 ml sterile solution.

Manufactured by :

GENERAL Pharmaceuticals Ltd.
Unit-2, Gazipur, Bangladesh

GENERAL Pharmaceuticals Ltd.
ISO 9001:2008 Certified Company