SUMMARY OF PRODUCTCHARACTERISTICS

1.7.1.1. Name of the medicinal Product

DICLOFENAC TABLETS BP

1.7.1.2 Qualitative and Quantitative Composition

1.7.1.3 Pharmaceutical Form

Oral Tablet

Orange coloured, round shaped, biconvex, enteric coated tablets, plain on both side.

1.7.1.4 Clinical Particulars

1.7.1.4.1 Therapeutic Indications

Diclofenac sodium is used for pain and inflammation in rheumatic disease (including juvenile idiopathic arthritis) and other musculoskeletal disorders; acute gout; postoperative pain.

1.7.1.4.2 Posology and Method of Administration

Adult: 75-150 mg daily in 2-3 divided doses.

Children (6 months to 18 years): Juvenile idiopathic arthritis: 1-3 mg/kg/day in divided

1.7.1.4.3 Contraindications

Hypersensitivity to the Diclofenac sodium or any of the excipients.

1.7.1.4.4 Special Warnings and Special Precautions for Use

Gastrointestinal: Bleeding, ulceration or gastrointestinal perforations, sometimes fatal, have been reported with all NSAIDs, including diclofenac. Diclofenac should also be used with caution in Crohn's disease or ulcerative colitis, as these conditions may be exacerbated.

Cardiovascular and cerebrovascular effects: It should be used with caution in patients with a history of cardiac failure, left ventricular dysfunction, hypertension, in patients with oedema for any other reason, and in patients with other risk factors for cardiovascular events. Diclofenac is associated with an increased risk of thrombotic events (e.g. myocardial infarction and stroke).

Asthmatic subjects: Patients with asthma associated with chronic rhinitis, chronic sinusitis with and/or nasal polyposis, have a risk of allergic reaction when taking aspirin and/or nonsteroidal anti-inflammatory drugs, higher than the rest of the population.

Elderly: The elderly have an increased risk of adverse reactions to NSAIDs especially gastrointestinal

bleeding and perforation which may be fatal.

Renal impairment: NSAIDs should be avoided if possible or used with caution in patients with renal impairment; the lowest effective dose should be used for the shortest possible duration, and renal function should be monitored.

Sodium and water retention may occur and renal function may deteriorate, possibly leading to renal failure.

Hepatic impairment: NSAIDs should be used with caution in patients with hepatic impairment; there is an increased risk of gastro-intestinal bleeding and fluid retention. NSAIDs should be avoided in severe liver disease.

1.7.1.4.5 Interaction with other medicinal products and other forms of interaction

Lithium: Increase in serum lithium concentrations and toxicity.

Cyclosporine, tacrolimus: Risk of additive nephrotoxic effects, especially in elderly patients.

Diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin If receptor antagonists: Increased risk of renal impairment when NSAIDs given with diuretics, ACE inhibitors or angiotensin-II receptor antagonists.

Adrenergic neuron blockers, aliskiren, alpha-blockers, Beta-blockers, calcium-channel blockers, clonidine, dazoxide, methyldopa, moxonidine, nitrates: NSAIDs antagonize hypotensive effect of these drugs.

Cardiac glycosides: NSAIDs possibly increase plasma concentration of cardiac glycosides, also possible exacerbation of heart failure and reduction of renal function.

Analgesics: Increased risk of toxicity. Avoid concomitant use with other NSAIDs.

Anticoagulants: Increased risk of haemorrhage diclofcnac given with anticoagulants (avoid concomitant use, including low-dose heparins); NSAIDs possibly enhance anticoagulant effect of coumarins and phenindione.

Antidepressants, corticosteroids, pentoxifyline: Increased risk of bleeding when NSAIDs.

Methotrexate: Increased hematological toxicity of methotrexate (decreased renal clearance by anti-inflammatory drugs).

1.7.1.4.6 Fertility, Pregnancy and Lactation

Pregnancy: Avoiding the use of NSAIDs during pregnancy or avoiding them unless the potential benefit outweighs the risk. NSAIDs should be avoided during the third trimester because use is associated with a risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn. In addition, the onset of abour may be delayed and its duration may be increased.

Breast-feeding: It should be used with caution during breast-feeding.

1.7.1.4.7 Effects on ability To Drive and use Machines

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

1.7.1.4.8 Undesirable Effects

Gastro-intestinal dish1rbances including discomfort, nausea, diarrhoea, and occasionally bleeding and ulceration occur. Other side-effects include hypersensitivity reactions (particularly rashes, angioedema, and bronchospasm), asthma, headache, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, tinnitus, photosensitivity, and haematuria. Blood disorders have also occurred. Fluid retention may occur (rarely precipitating congestive heart failure) ; blood pressure maybe raised. Renal failure may be provoked by NSAIDs, especially in patients with pre-existing renal impairment. Hepatic damage, alvcolitis, pulmonary eosinophilia, pancreatitis, visual disturbances, and toxic epidermal necrolysis are other rare side-effects. Induction of or exacerbation of colitis or Crohn's disease has been reported.

1.7.1.4.9 Overdose

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, tinnitus, fainting, occasionally, convulsions. In rare cases of significant poisoning acute renal failure and liver damage are possible. Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered.

1.7.1.5 Pharmacological Properties

1.7.1.5.1 Pharmacodynamics Properties

Diclofenac sodium is a non-steroidal agent with analgesic, antipyretic and anti-inflammatory properties. It is an inhibitor of prostaglandin synthetase (cyclooxygenase).

1.7.1.5.2 Pharmacokinetic Properties

Diclofenac is rapidly and completely absorbed. The oral bioavailability is 50% due to the effect of first pass metabolism. More than 99% of diclofenac is reversibly bound to human plasma albumin. Diclofenac diffuses into synovial fluid, where maximum concentrations are measured 2-4 hours after

peak plasma. Diclofenac is rapidly metabolized and almost completely, mainly in the liver. The major routes of metabolism are hydroxylation and glucuronidation. Excretion is both urinary and fecal incontinence. Less than I% of the active substance is excreted unchanged in the urine. Approximately 60% of the amount administered is excreted as metabolites in the urine; the remainder is excreted in the feces. The half life in plasma of unchanged diclofenac is around 1 to 2 hours.

1.7.1.5.3 Preclinical Safety Data

Preclinical data from acute and repeated dose toxicity studies, as well as from genotoxicity, mutagenicity, and carcinogenicity studies with diclofenac revealed no specific hazard for humans at the intended therapeutic doses. In standard preclinical animal studies, there was no evidence that diclofenac had a teratogenic potential in mice, rats or rabbits.

Diclofenac has no influcence on the fertility of parent animals in rats. Except for minimal fetal effects at maternally toxic doses the prenatal, perinatal and postnatal development of the offspring was not affected.

Administration of NSAIDs (including diclofenac) inhibited ovulation in the rabbit and implantation and placentation in the rat, and led to premature closure of the ductus arteriosus in the pregnant rat. Maternally toxic doses of diclofenac were associated with dystocia, prolonged gestation, decreased fetal survival, and intrauterine growth retardation in rats.

1.7.1.6 Pharmaceutical Particulars

1.7.1.6.1 List of Excipients

Povidone (P.V.P.K.-30) BP
Isopropyl Alcohol BP
Microcrystalline Cellulose (PH 102) BP
Purified Talc BP
Sodium Starch Glycolate (Type-A) BP
Colloidal Anhydrous Silica BP
Magnesium Stearate BP
Spraycel SC-AQE-9002
Diethyl Phthalate BP
Purified Water BP

1.7.1.6.2 Incompatibilities

Not applicable.

1.7.1.6.3 Shelf Life

36 months

1.7.1.6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

1.7.1.6.5 Nature and Contents of Container

10 Tablets are in Blister Pack. Such 10 Blisters are packed in Printed Carton with Packing Insert.

1.7.1.6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

1.7.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.7.1.7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-02764-665000

Fax: +91-02764-281809

Email: info@lincolnpharma.com

Website: www.lincolnpharma.com

1.7.1.7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-02764-665000

Fax: +91-02764-281809

Email: info@lincolnpharma.com

Website: www.lincolnpharma.com

1.7.1.8 Marketing Authorization Number

06853/07713/NMR/2019

1.7.1.9 Date of First <Registration> / Renewal of The <Registration>

Nov 28, 2021

1.7.1.10 Date of Revision of the Text

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1.7.1.11 Dosimetry (If Applicable)

Not Applicable

1.7.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable