SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENERIC: Gastro-Resistant Diclofenac Tablets BP 50mg
BRAND NAME: DICLOKANT-50

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each enteric coated tablet contains:
Diclofenac Sodium BP …… 50 mg
Excipients ….....…..q.s
Colour: Sunset Yellow FCF

3. PHARMACEUTICAL FORM:

Solid Oral Dosage Form – Tablets.
Orange colored, enteric coated, circular, biconvex tablets plain on both sides.

4.CLINICAL PARTICULARS

4.1 Therapeutic Indication:

Inflammatory and degenerative forms of rheumatism : rheumatoid arthritis and osteoarthritis for back pain.
Relief of acute or chronic pain states in which there is an inflammatory component.
Symptomatic treatment of primary dysmenorrhoea.

4.2 Posology and method of administration:

Usual Adult dose:
25 to 50 mg taken three times daily. Initially this dose may be increased to 150 mg daily and may be reduced to 75 to 100 mg daily in milder cases or for long-term and maintenance therapy. Diclofenac sodium is not recommended for use in children as safety and efficacy have not been established.
The dose in children is 2 mg per kilogram body mass per day in three divided doses.
The tablets should be swallowed whole, with or after a meal.
Method of administration: Oral

4.3 Contraindications:

Hypersensitivity to the active substance or any of the excipients.

• Active, gastric or intestinal ulcer, bleeding or perforation.
• History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy
• Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
• Last trimester of pregnancy
• Severe hepatic, renal or cardiac failure
• Like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac is also contraindicated in patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by ibuprofen, acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs.

4.4 Warning and precautions for use

Acute allergic reactions have been reported. Because of the possibility of cross sensitivity due to structural relationship which exist among non-steroidal anti inflammatory medicines, acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds. Allergic reactions which include angio-oedema, bronchospasm, urticarial, and anaphylactic reactions, have occurred.

In view of the products inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.Plasma concentrations are significantly decreased by the concomitant administration of therapeutic doses of aspirin.When given together with preparations containing lithium or digoxin, diclofenac sodium may raise their plasma concentrations.Concomitant administration of glucocorticoids or other non-steroidal anti-inflammatory agents may aggravate gastro-intestinal side-effects.

Concurrent administration with two or more non-steroidal anti-inflammatory agents may promote the occurrence of side-effects. Should be used with caution in patients with asthama or bronchoconstriction.

Use carefully in elderly patients.

Decreased platelet aggregation with increased bleeding time may occur.May increase the half-life of probenecid.

Use with care together with other protein-bound medicines e.g. Tolbutamine, coumarin and hydantoin.

4.5 Drug Interactions

Other analgesics including cyclooxygenase-2 selective inhibitors : Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk of adverse effects.

Anti-hypertensive : Reduced anti-hypertensive effect.

Diuretics: Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Cardiac glycosides: NSAIDS may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

Lithium: Decreased elimination of lithium

Methotrexate: Decreased risk of nephrotoxicity.

Mifepristone: NSAIDs can reduce the effect of mifepristone.

Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding.

Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin.

Quinolone Antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and Quinolones may have an increased risk of developing convulsions.

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs):

Increased risk of gastrointestinal bleeding

Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with Zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

4.6 Fertility Pregnancy & Lactation

Pregnancy

Congenital abnormalities have been reported in association with NSAID administration in man, however, these are low in frequency and do not appear to follow any discernible pattern. In view of the known effects of appear to follow any discernible pattern. In view of the known effects of NSAIDs on the foetal cardiovascular system (risk of closure of the ductus arteriousus), use in the last trimester of pregnancy is contraindicated. The onset of labour may be delayed and the duration increased with an increased bleeding tendancy in both mother and child. NSAIDs should not be used during the first two trimesters of pregnancy or labour unless the potential benefit to the patient outweighs the potential benefit to the patient outweighs the potential risk to the foetus.

Lactation

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

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.

4.8 Adverse Effects

Gastrointestinal experiences including: abdominal pain, constipation, diarrhea, dyspepsia, flatulence gross bleeding/perforation, heartburn, nausea, Glulcers (Gastric/duodenal) and vomiting.

Abnormal renal function, anemia, dizziness, edema, elevated liver enzymes, headaches, increased bleeding time, pruritus, rashes and tinnitus.

4.9 Overdose

a) Symptoms

Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, fainting and occasionally convulsions. In cases of significant poisoning acute renal failure and liver damage are possible.

b) Therapeutics measure

Patients should be treated symptomatically as required.

Within one hour of ingestion of potentially life-threatening overdose.

Good urine output should be ensured.

Renal and liver function should be observed for at least four hours after ingestion of potentially toxic amounts.

Frequent or prolonged convulsions should be treated with intravenous diazepam.

Other measures may be indicated by the patients clinical condition.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Diclofenac sodium is non-steroidal compound, a phenylacetic acid derivative with analgesic, antipyretic and anti-inflammatory effects. Diclofenac sodium inhibits the biosynthesis and release of prostaglandins which are known to be implicated in the pathogenesis of inflammation, pain and fever.

5.2 Pharmacokinetic properties

Diclofenac sodium is completely absorbed from the intestinal tract but undergoes first pass metabolism and peak plasma concetrations occur in about 2 to 4 hours; at therapeutic concentrations it is more than 99% bound to plasma proteins. Diclofenac is almost entirely metabolized in the liver and the terminal plasma half life is about 1-2 hours, with metabolic excretion mainly via the kidneys and also in the bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch, Lactose monohydrate, Povidone (PVP K 30), Purified water, Magnesium Stearate, Purified Talc, Wincoat-WTN 01062-Orange, Dichloromethane, Isopropyl Alcohol

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months

6.4 Special precautions for storage:

Do not store above 30°C. Protect from light.

Keep the medicine out of reach of children.

6.5 Nature and contents of container

10 Tablets in a Aluminium PVC blister & such 10 blisters in a carton along with the Insert.

7. APPLICANT

Manufactured by:

S Kant
HEALTHCARE Ltd.
Factory address:1802-1805, G.I.D.C., Phase III,
Vapi - 396 195. Gujarat, INDIA.
Head office: 3 - A, Shivsagar Estate, Dr.
Annie Besant Road,
Worli, Mumbai 400 018, India
Tel.: 0091 - 22 - 6622 7575 (Board Line)
Fax: 0091 - 22 - 6622 7500
Email: kalpesh@sk1932.com

8. NATIONAL REGISTRATION NUMBER

07266/09518/NMR/2022

9. DATE OF AUTHORISATION

11/04/2022

10. DATE OF REVISION OF THE TEXT

10/02/2017