· Drug Category : Nonsteroidal antiinflammatory drugs

TAPAIN Inj.

Diclofenac sodium 75mg

■ DESCRIPTION

Each ampoule(2mL) contains 75mg of Diclofenac sodium.

■ INDICATIONS

This drug can be used for the following diseases ; rheumatoid arthritis, osteoarthrosis (degenerative form of rheumatism), ankylosing spondylitis, the relief of pain and inflammation in post-operation and trauma, acute gout, renal and biliary colic.

■ DOSAGE & ADMINISTRATION

For adults the dosage is generally one ampoule(75mg as Diclofenac sodium) once daily, injected intramuscularly by deep intragluteal injection into the upper outer quadrant. In severe cases, Two injections, separated by an interval of a few hours, can be given per day. In such a case, it is advised that the alternate buttock be used for the second injection. Following the initial period of treatment, the treatment must be continued with a tablets or suppositories. If needed, this dose may be increased or decreased according to the age of patients and/or the severity of symptoms.

■ PRECAUTIONS

1. Warning

The patients who drink more than 3glasses of alcoholic liquor every day should consult a doctor or a pharmacist. GI haemorrhage may occur in these patients.

2. Do not administer to the following patients.

1) Patients with peptic ulcer
2) Patients with severe haematological abnormalities
3) Patients with severe hepatic disturbances
4) Patients with severe renal disturbances
5) Patients with severe hypertension
6) Patients with severe cardiac failure
7) Patients with hypersensitivity to Diclofenac sodium
8) Patients with a history of allergosis(e.g. asthma, urticaria, etc) by this drug or other NSAIDs(e.g. Aspirin)

3. Administer cautiously to the following patients.

1) Patients with a history of peptic ulcer
2) Patients with haematological abnormalities or the history
3) Patients with hepatic, renal disturbances or the history
4) Patients with hypertension
5) Patients with cardiac failure
6) Patients with SLE(systemic lupus erythematosus)
7) Patients with a history of hypersensitivity
8) Patients with bronchial asthma
9) Patients with ulcerative colitis
10) Patients with Crohn's disease
11) Patients with oesophageal lesions
12) The elderly, children and infants

4. Adverse effects

1) Shock : Rarely shock(e.g. anxiety of the breast, cold, dyspnoea, sense of quadriplegia, descent of blood pressure, edema, eruption, itching, etc) may occur. In such a case, discontinue the therapy and take appropriate measures.
2) Gastro-intestinal tract : Rarely peptic ulcer, gastro-intestinal bleeding, oesophagial ulcer and perforation may occur. In such a case, dis-continue the therapy.
3) Blood : Rarely granulocytopenia, decreased hemoglobin, leucopenia, thromb-ocytopenia, anaemia, aplastic anaemia, haemolytic anaemia, bleed-ing tendency, purpura and allergic purpura may occur.
4) Skin : Rarely Stevens-Johnson's syndrome(mucocutaneousocular syndrome), Lyell's syndrome(acute toxic epidermolysis), photosensitivity reactions, rashes, itching, eczema, dermatitis, vasogenic edema, erythema multiforme, flushing and exudative dermatitis may occur. In such a case, discontinue the therapy and take appropriate meas-ures.
5) Liver : Rarely hepatitis, jaundice, hepatic disturbance and elevation of GOT and GPT may occur. Especially, take care of concomitant trea- tment with gold preparations.
6) Kidney : Rarely acute renal insufficiency may occur. In cases of oliguria, proteinuria, increase in BUN and creatinine and hyperkalemia, immediately discontinue the therapy and take appropriate measures.
7) Hypersensitivity : Rarely asthma attack, occasionally eruption, urticaria, etc. may occur. In such a case, discontinue the therapy and take appropriate measures.
8) Psychoneurotic : Insomnia, depression, hypersensibility, anxiety and dip- lopia may occur. Rarely headache, drowsiness, dizziness, paralysis, confusion, hallucination and convulsion may occur.
9) Sensory : Rarely disturbance of vision(blurred vision), tinnitus, etc. may occur. Transient pain, dryness, itching, superficial keratitis, etc. may occur.
10) Circulatory organs : Rarely elevation or descent of blood pressure, palpi- tation, tachycardia, congestive heart failure, ventricular extra-systole, myocardial infarction, etc. may occur.
11) Respiratory system : Occasionally epistaxis(nasal bleeding), asthma, phar-yngeal edema, etc. may occur.
12) Urinary organ : Pollakisuria, nyctalopia, impotence and vaginal bleeding may occur.
13) Others : Occasionally edema, rarely general fatigue, sweating, etc. may occur.

5. General precautions

1) It should be noted that treatment with an antiinflammatory and analgesic drug is not a causal but symptomatic therapy.
2) The following considerations should be taken into when this drug is used for chronic diseases.
   (1) In the case of a long-term therapy, perform the laboratory examinat-ion(urine, blood, hepatic function test, etc.). When abnormalities have been observed, take appropriate measures such as decreasing the dose or discontinuing the therapy.
   (2) It is advisable to consider other therapies besides medicine therapy.
3) The following considerations should be taken into when this drug is used for acute diseases.
   (1) Administer this drug by considering the severity of acute inflammation, pain and fever.
   (2) In principle, avoid long-term administration with the same drug.
   (3) If there is causal therapy, carry out that.
4) The condition of the patients should be monitored carefully with particular attention to the onset of the side effects. Care should be taken of the condition of patients, after the administration of this drug, especially in children with severe fever, infants, the elderly and patients with consumption, because symptoms such as excessive descent of body temperature, collapse, quadrifrigidus, etc. may occur.
5) It is advisable not to administer this drug concomitantly with other anti- inflammatory and analgesic drugs.
6) In the elderly and children, the dosage should be restricted to the minimum required level. And care should be taken of the onset of side effects.
7) Even in patients who have never been received treatment with this drug, reactions such as edema of eyelids, lip, pharynx and larynx, urticaria asthma, bronchial spasm, descent of blood pressure, etc. may occur.

6. Drug interactions

1) As concomitant treatment with lithium preparations, digoxin and methotrexate preparations may potentiate their effects, administer them carefully e.g. decreasing those drugs.
2) Concomitant treatment with aspirin may decrease the effect.
3) Concomitant treatment with furosemide may decrease the effect.
4) Concomitant treatment with adrenocortical hormones may increase the mutual adverse-effects.
5) It is reported that concomitant treatment with coumarin anticoagulants increase their risk of bleeding. Therefore, such a administration should be carried out under careful surveillance of the patients such as coagul- ation test, etc.

7. Use in pregnancy and lactation

1) As the safety during pregnancy has not yet been established, it should be used during pregnancy or suspected pregnancy only if the potential benefit justifies the potential risk.
2) It is reported that administration during the last trimester of pregnancy cause the PFC. Such drugs are therefore not recommended during the last trimester of pregnancy.
3) It is reported that administration to the rat during the last trimester of pregnancy causes arteriocontraction.
4) It is reported that this drug is excreted in human milk.

8. Use in neonates, infants and children

1) As neonates and infants generally have a incomplete regulation mechanism of body temperature, administration of this drug may cause a excessive descent of body temperature. Therefore, this drug must be administered to neonates and infants only when they have the symptoms e.g. excessive elevation of temperature.
2) The safety in children has not yet been established.

9. Overdosage

1) Symptoms and signs : The report on the overdosage is insufficient. And the typical clinical symptoms have not yet been established.
2) Measures : In case of overdosage caused by NSAIDs, generally take the fol- lowing measures ; In case of hypotension, renal insufficiency, convulsion, gastrointestinal disorders and depression of respiration, symptomatic therapy should be performed. In case of high protein binding rate, measures such as forced urination, blood dialysis, etc. are not useful for the elimination of Diclofenac.

■ **STORAGE**
Hermetic container protected from light at room temperature(1-30℃)

■ **SHELF LIFE**
36 months

■ **PACKAGE**
2mL x 50A/Box

※ Medicine : Keep out of reach of children.