

# Diclofenac Gastro-Resistant Tablets BP 100 mg



## Composition:

Each enteric coated tablet contains:

Diclofenac sodium BP..... 100 mg

Excipients .....qs

Approved colour used.

**Dosage:** Diclofenac Sodium: 50 mg orally 2 to 3 times a day or 75 mg orally twice a day. Doses greater than 150 mg/day are not recommended for osteoarthritis. Or as directed by your doctor.

## Indications:

- 1) Control pain and inflammation in rheumatoid arthritis, other rheumatic conditions, bursitis and tendonitis
- 2) As an alternative to indomethacin in controlling acute gout attacks
- 3) Dimenorrhea
- 4) Acute intense pain. Mild, moderate to severe (post-operative pain) as a sole analgesic (mild pain) or associated with opioids (moderate to severe pain)

## Secondary effects:

Dyspepsia, nausea, vomiting, diarrhea or constipation, headache, vertigo, tinnitus, drowsiness and transient elevation of hepatic transaminases frequently occur. More rarely, mental confusion, gastroduodenal ulcer and digestive hemorrhage may occur, or water retention may worsen hypertension or precipitate heart failure, especially in elderly patients. It may precipitate renal failure, especially in elderly patients, with nephropathy, liver cirrhosis, systemic lupus erythematosus, arterial hypotension, withdrawal or concomitant treatment with diuretics. Hypersensitivity reactions manifested by bronchospasm (especially in asthmatics), skin rash, itching, urticaria and angioedema particularly in patients sensitive to ASA or other NSAIDs. There may be inhibition of platelet aggregation, rarely hematological disorders such as aplastic anemia, hemolytic anemia, agranulocytosis.

## Contraindications:

Hypersensitivity to AAS or other AINS, active peptic ulcers, severe renal, hepatic or cardiac insufficiency, uncontrolled hypertension.

## Precautionary notes:

- Avoid or use with caution in patients with mild or moderate renal, cardiac or hepatic insufficiency and in hypertensive patients or with a psychiatric history (these situations may worsen).
- Avoid or use with great caution in patients with a history of peptic ulcers and in elderly patients
- The risk of gastric ulcer or digestive bleeding increases with age, when associated with other substances such as alcohol, tobacco, corticosteroids, ASA and in cases of liver or

kidney failure.

- It should not be used in patients with bleeding disorders, atopy, asthma, nasal polyps or urticaria.
- Simultaneous use of anticoagulants increases the risk of bleeding
- Do not use in combination with other NSAIDs due to risk of dose enhancement
- Simultaneous use with glucocorticoids may increase the toxicity of both drugs
- Increases the levels of lithium salts, by decreasing the renal clearance of this drug
- Increases methotrexate levels and toxicity.
- May alter response to digoxin.
- Decreases the effectiveness of antihypertensives and other medications used to treat angina, heart failure, including diuretics
- It can increase the therapeutic effect of drugs with which it competes in binding plasma proteins (sulfonamides, sulfonylureas, phenytoin, verapamil and nifedipine), disconnecting them from this binding.
- Probenecid may inhibit its elimination.
- The association with drugs that cause hypoprothrombinemia and/or inhibition of platelet aggregation increases the risk of hemorrhage (penicillins, cephalosporins, dipyridamole and valproic acid).
- Use during pregnancy is not recommended, administration during the third trimester is associated with antepartum and postpartum hemorrhage and premature closure of the ductus arteriosus.
- Can be used during lactation
- Prolonged use (longer than 1 week) increases the risk of toxicity.
- Oso simultaneously with opioids in intense treatment reduces the need for the latter.
- Safety for children under 2 years of age has not been established.
- It is recommended to take with food to reduce gastrointestinal irritating effects.

**Storage:** Store in a cool, dark and dry place, below 30°C.

**Keep the medicine out of the reach of children.**

**Presentation:** Blister of 10 tablets

Manufactured by:



JOINT PAIN



PAIN AND DISTENSIONS



BACKACHE

