Motaar

(Diclofenac Sodium / Acid)

TABLETS
INJECTION

ANTI-RHEUMATIC, ANTI-INFLAMMATORY & ANALGESIC

COMPOSITION AND FORM OF ISSUE
Active ingredient: sodium [0-(2,6-dichloroanilino)phenyl] acetate (=diclofenac sodium)

PHARMACEUTICAL FORM
- **MOTAAR 50 mg tablet**
  Each Tablet contains: Diclofenac sodium (B.P).....50 mg
- **MOTAAR Dispersible 50 tablet**
  Each Dispersible tablet contains: Diclofenac acid.....50 mg
- **MOTAAR SR 100 mg tablet**
  Each sustained release tablet contains:
  Diclofenac sodium (B.P).....100 mg
- **MOTAAR Injection**
  Each ampoule of 3ml contains: Diclofenac sodium (B.P).....75 mg

CLINICAL INDICATIONS
- Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism.
- Acute attacks of gout.
- Post-traumatic and post-operative pain, inflammation and swelling, e.g. following dental or orthopaedic surgery.
- Painful and / or inflammatory conditions in gynaecology e.g. primary dysmenorrhoea or adnexitis.
- As an adjuvant in severe painful inflammatory infections of the ear, nose, or throat, e.g. pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.
- Renal colic and biliary colic.
- Severe migraine attacks.

DOSAGE AND ADMINISTRATION
ADULTS
The recommended initial daily dosage is 100-150 mg. In milder cases, as well as for long-term therapy, 75-100 mg daily is usually sufficient. The total daily dosage should be divided into 2-3 doses. In primary dysmenorrhoea the daily dosage should be individually adjusted and is generally 50-150 mg. Initially a dose of 50-100 mg should be given and, if necessary, raised in the course of several menstrual cycles up to a maximum of 200 mg / day. Treatment should be started upon appearance of the first symptom and, depending on the symptomatology, continued for a few days. The Tablets should be swallowed whole with liquid preferably before meals.
MOTAAR injections should not be given for more than 2 days; if necessary, treatment can be continued with **MOTAAR** tablets.

CHILDREN
Children aged 1 year or over should be given 0.5-2 mg/kg body weight daily, in 2-3 divided doses, depending on the severity of the disorder. For treatment of juvenile rheumatoid arthritis the daily dosage can be raised up to a maximum of 3 mg/kg, in divided doses.

INTRAMUSCULAR INJECTION
The following directions for intramuscular injection must be followed in order to avoid damage to nerve or other tissue at the injection site.
The dosage is generally one 75mg ampoule daily, given by deep intragluteal injection into the upper outer quadrant. In severe cases (e.g. colic) the daily dose can exceptionally be increased to two injections of 75mg, separated by an interval of a few hours (one into each buttock).

Alternatively, one ampoule of 75mg can be combined with other dosage forms of **MOTAAR** up to a maximum daily dosage of 150mg. In migraine attacks, clinical experience is limited to initial use of one injection of 75mg administered as soon as possible, followed by **MOTAAR** tablets. The total dosage should not exceed 175mg on the first day.

INTRAVENOUS INFUSION
MOTAAR must not be given as an intravenous bolus injection. Immediately before starting an intravenous infusion **MOTAAR** must be diluted with saline 0.9% or glucose 5% infusion solution buffered with sodium bicarbonate according to the instructions given in the section "Instructions for use/handling". Two alternative dosage regimens of **MOTAAR** are recommended.
For the treatment of moderate to severe postoperative pain, 75mg should be infused continuously over a period of 30 minutes to 2 hours. If necessary, treatment may be repeated after a few hours, but the dosage should not exceed 150mg within any period of 24 hours. For the prevention of postoperative pain, a loading dose of 25-50mg should be infused after surgery over 15 minutes to 1 hour, followed by a continuous infusion of about 5mg per hour up to a maximum daily dosage of 150mg.

CHILDREN
MOTAAR injections are not recommended for use in children.

CONTRA INDICATIONS
Gastric or intestinal ulcer.
Known hypersensitivity to the active substance, or sodium metabisulphite and other excipients. Like all other non-steroidal anti-inflammatory drugs (NSAIDs), **MOTAAR** is also contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other drugs with prostaglandin-synthetase inhibiting activity.

WARNINGS AND PRECAUTIONS
Gastrointestinal bleeding or ulceration / perforation can occur at any time during treatment, with or without warning symptoms or a previous history. They generally have more serious consequences in the elderly. In the rare cases where gastrointestinal bleeding or ulceration occurs in patients receiving **MOTAAR**, the drug should be withdrawn. As with other NSAIDs, allergic reactions, including anaphylactic / anaphylactoid reactions, can also occur in rare cases without earlier exposure to the drug.
Like other NSAIDs, **MOTAAR** may mask the signs and symptoms of infection due to its pharmacodynamic properties.
Only clear solution should be used. If crystals or precipitate are observed, the infusion should not be used.

PRECAUTIONS
Close medical surveillance is imperative in patients with symptoms indicative of gastrointestinal disorders, with a history of gastric or intestinal ulceration, in patients with Ulcerative colitis or Crohn's disease, and in patients suffering from impaired hepatic function. As with other NSAIDs, values of one or more liver enzymes may increase. During prolonged treatment with **MOTAAR** monitoring of hepatic function is indicated as a precautionary measure. If abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (e.g. eosinophilia, rash, etc.) **MOTAAR** should be discontinued. Hepatitis may occur without prodromal symptoms. Caution is called for when using **MOTAAR** in patients with hepatic porphyria, since it may trigger an attack.
Owing to the importance of prostaglandins in maintaining renal blood flow, particular caution is called for in patients with impaired cardiac or renal function, the elderly, patients being treated with diuretics, and patients with substantial extracellular volume depletion from any cause, e.g. before or after major surgery. Monitoring of renal function is recommended as a precautionary measure when using **MOTAAR** in such cases. Discontinuation of therapy is usually followed by recovery to the pretreatment state.
During prolonged treatment with **MOTAAR**, as with other NSAIDs, monitoring of the blood count is recommended. Like other NSAIDs,

MOTAAR may temporarily inhibit platelet aggregation. Patients with haemostatic disorders should be carefully monitored. Caution is indicated in the elderly on basic medical grounds. In particular, it is recommended that the lowest effective dosage be used in frail elderly patients or those with a low body weight.

DRUG INTERACTIONS
LITHIUM, DIGOXIN: MOTAAR may raise plasma concentration of lithium and digoxin.
DIURETICS: like other NSAIDs, **MOTAAR** may inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels, which should therefore be monitored frequently.
NSAIDs: Concomitant administration of systemic NSAIDs may increase the frequency of undesirable effects.
ANTICOAGULANTS: Although clinical investigations do not appear to indicate that **MOTAAR** affects the actions of anticoagulants, there are isolated reports of an increased risk of haemorrhage in patients receiving **MOTAAR** and anticoagulants concomitantly. Close monitoring of such patients is therefore recommended.
ANTIDIABETICS: Clinical studies have shown that **MOTAAR** can be given together with oral antidiabetic agents without influencing their clinical effects. However, isolated cases have been reported of both hypoglycaemic and hypergiycaemic effects necessitating changes in the dosage of hypoglycaemic agents during treatment with **MOTAAR**.
METHOTREXATE: Caution is called for when NSAIDs are administered less than 24 hours before or after treatment with methotrexate, since blood concentrations of methotrexate may rise and toxicity of this substance be increased.
CYCLOSPORIN: The effects of NSAIDs on renal prostaglandins may increase the nephrotoxicity of cyclosporin.
QUINOLONE ANTIBACTERIALS: There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.

PREGNANCY AND LACTATION
During pregnancy, **MOTAAR** should be employed only for compelling reasons and only in the lowest effective doses. As in the case of other prostaglandin-synthetase inhibitors, this applies particularly to the last 3 months of pregnancy (owing to the possibility of uterine inertia and / or premature closure of ductus arteriosus.) Following oral doses of 50 mg administered every 8 hours, the active substance passes into the breast milk, but in quantities so small that no undesirable effects on the infant are to be expected. Because of insufficient data, administration of **MOTAAR** injections during pregnancy and lactation is not recommended.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE
Patients experiencing dizziness or other central nervous disturbances including visual disturbances, should not drive or operate machinery.

UNDESIRABLE EFFECTS
(including undesirable effects observed with other dosage forms of **MOTAAR** either in short-term or long-term use). The following frequency estimates were used: frequent >10%, occasional >1% to 10%, rare>0.001% to 1% isolated cases < 0.001%.
GASTROINTESTINAL TRACT: Occasional: epigastric pain, nausea, diarrhea, abdominal cramps, dyspepsia, flatulence, anorexia. Rare: gastrointestinal bleeding (haematemesis, melena, bloody diarrhoea), gastric or intestinal ulcer with or without, bleeding or perforation.
ISOLATED CASES: aphthous stomatitis, glossitis, oesophageal lesions, diaphragm-like intestinal strictures, lower gut disorders such as nonspecific haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease; constipation, pancreatitis.
Central nervous system: Occasional: headache, dizziness, vertigo.
RARE: drowsiness
ISOLATED CASES: sensory disturbances, including paraesthesia, memory disturbances, disorientation, insomnia, irritability, convulsions, depression, anxiety, nightmares, tremor, psychotic reaction, aseptic meningitis.
SPECIAL SENSES: Isolated cases: disturbances of vision (blurred vision, diplopia) impaired hearing, tinnitus, taste disturbances. Skin: Occasional: rashes or skin eruptions.
RARE: URTICARIA. ISOLATED CASES: bullous eruptions, eczema, erythema multiforme, Stevens Johnson syndrome, Lyell's syndrome (acute toxic epidermolysis), erythroderma (exfoliative dermatitis), loss of hair, photosensitivity, purpura, including allergic purpura. Liver: Occasional: elevation of serum aminotransferase enzymes Rare: hepatitis with or without jaundice.
ISOLATED CASES: fulminant hepatitis.
BLOOD: Isolated cases: thrombocytopenia, leucopenia, haemolytic anaemia, aplastic anaemia, agranulocytosis.
HYPERSENSITIVITY RARE: hypersensitivity reactions such as asthma, systemic anaphylactic anaphylactoid reactions including hypotension. Isolated cases: vasculitis, pneumonitis.
CARDIOVASCULAR SYSTEM: Isolated cases: palpitation, chest pain, hypertension, congestive heart failure.
OTHER ORGAN SYSTEMS: Occasional: intramuscular injection site reactions such as local pain and induration.
ISOLATED CASES: local abscesses and necrosis at the intramuscular injection site.

INSTRUCTIONS FOR USE/HANDLING
MOTAAR solution for injection should not be mixed with other injection solutions. **MOTAAR** injection can be given either intramuscularly by deep intragluteal injection into the upper outer quadrant, or intravenously by slow infusion after dilution in accordance with the following instructions.
Depending on the intended duration of infusion (see section "Doses and administration") mix 100-500 ml of isotonic saline (sodium chloride 0.9% solution) or glucose 5% solution with sodium bicarbonate injectable solution (0.5 ml of 8.4% or 1 ml of 4.2% or a corresponding volume of different concentration) taken from freshly opened container; add the contents of one **MOTAAR** injection to this solution. Only clear solutions should be used. If crystals or precipitates are observed, the infusion solution should not be used. Infusion solution of sodium chloride 0.9% or glucose 5% without sodium bicarbonate as an additive present a risk of supersaturation, possibly leading to formation for crystals or precipitates. Infusion solution other than those recommended should not be used. Intravenous infusions should be initiated immediately after preparing the infusion solutions. The infusion solutions should not be stored.

INSTRUCTIONS
Store in cool & dry place. Protect from light. Keep out of reach of children. To be sold on the prescription of a registered medical practitioner only. Avoid freezing & injection should not be used if ampoule is leaking, solution is cloudy or contains undissolved particles.

PRESENTATION
Motaar Tablets 50mg, 20's in blister packing.
Motaar Tablets Dispersible 50 mg, 20's in blister strip.
Motaar Tablets SR 100mg, 30's in blister packing.
Motaar Injection 10 ampoule (3ml) of 75mg.

موٹار ٹیبلیٹس/انجکشن
(ڈکلوفینک سوڈیم)

ہدایات: خشک اور ٹھنڈی جگہ پر رکھیں۔ روشنی سے بچائیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔
مُجمد ہونے سے بچائیں۔ انجکشن کے ایک ہونے دھندلا ہونے یا اس میں کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔

Manufactured by:
STANDPHARM PAKISTAN (PVT) LTD
20 km Ferozepur Road Lahore, Pakistan.