CHLORZOXAZONE, DICLOFENAC SODIUM & PARACETAMOL TABLETS

VIVIAN-MR

POM

IDENTIFICATION: Orange coloured, capsule shaped, film coated tablets, plain on both sides.

COMPOSITION:
Each film coated tablet contains:
Chlorzoxazone USP 250 mg
Diclofenac Sodium BP 50 mg
Paracetamol BP 325 mg
Excipients Q.S
Approved colour used

EXCIPIENTS:
Croscarmellose sodium, Microcrystalline cellulose (PH 102), Povidone (PVPK30), Maize starch, Sodium lauryl sulfate, Propylene glycol, Sodium starch glycolate (TYPE A), Colloidal anhydrous silica (AEROSIL), Magnesium stearate, Isopropyl alcohol, Dichloromethane, Colour sunset yellow orange SCSP2029, Purified water.

PHARMACOLOGICAL CLASSIFICATION:
Muscle Relaxants, Analgesic, Anti-inflammatory, Antipyretic.

PHARMACOLOGICAL ACTION:
Chlorzoxazone is a centrally acting agent for painful musculoskeletal conditions. Chlorzoxazone acts primarily at the level of the spinal cord and subcortical areas of the brain where it inhibits multisynaptic reflex arcs involved in producing and maintaining skeletal muscle spasm of varied etiology. The clinical result is a reduction of the skeletal muscle spasm with relief of pain and increased mobility of the involved muscles.
Diclofenac sodium is reversibly inhibits cyclooxygenase-1 and 2 (COX-1 and COX-2) enzymes, which results in decreased formation of prostaglandin precursors in the epithelium of the stomach.
Paracetamol inhibits the synthesis of prostaglandins in the central nervous system and peripherally blocks pain impulse generation. Paracetamol produces antipyresis from inhibition of hypothalamic heat-regulating center.

PHARMACOKINETIC:
CHLORZOXAZONE:
Absorption: After oral administration Chlorzoxazone is rapidly and completely absorbed from gastrointestinal tract. Peak levels may be reached in about 1 to 2 hours
Distribution: The plasma elimination half-life is about 1 hour for chlorzoxazone. Protein binding is about 13-18%.
Metabolism and Excretion: Chlorzoxazone is rapidly metabolized in liver, mainly to 6-hydroxy chlorzoxazone and is excreted in the urine, primarily in a conjugated form as the glucuronide. Less than 1% of a dose of chlorzoxazone is excreted unchanged in the urine in 24 hours.

DICLOFENAC SODIUM:
Absorption: Diclofenac sodium is rapidly absorbed from the gut and is subject to first-pass metabolism. Tablets give peak plasma concentrations after 1-4 hours.
Distribution: The apparent volume of distribution of diclofenac sodium is 1.4 L/kg. Diclofenac is more than 99% bound to human serum proteins, primarily to albumin.
Metabolism and Excretion: due to first-pass metabolism, only about 50% of the absorbed dose is systemically available. Diclofenac is eliminated through metabolism and subsequent urinary and biliary excretion of the glucuronide and the sulfate conjugates of the metabolites. Approximately 60% of the administered dose is excreted via the kidneys in the form of metabolites and less than 1% in unchanged form. The remainder of the dose is excreted via the bile in metabolized form.

PARACETAMOL:
Absorption: Paracetamol is rapidly and almost completely absorbed from gastrointestinal tract with peak plasma concentrations (Cmax) occurring about 10 to 60 minutes after oral administration.
Distribution: Plasma protein binding is negligible at usual therapeutic concentration but increases with increasing concentrations. It is relatively uniformly distributed throughout most body fluids. The plasma half life (t1/2) 2-3 hours and the effect after oral dose lasts for 3-5 hours.
Metabolism and Excretion: Paracetamol is metabolized predominantly in liver and excreted in the urine mainly as glucuronide and sulfate conjugate. Less than 5% is excreted unchanged.

INDICATIONS:
Chlorzoxazone, Diclofenac sodium & Paracetamol Tablets is indicated in the following situations:
Soft tissue injuries with spam and inflammation,
Neck pain, Shoulder pain, back pain,
Tendonitis, tenosynovitis, bursitis,
Musculoskeletal disorders

CONTRAINDICATIONS:
Chlorzoxazone, Diclofenac sodium & Paracetamol Tablets is contraindicated in the Patients with hypersensitivity to any component of the formulation.

SPECIAL PRECAUTIONS AND WARNING:
Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSRIs) or anti-platelet agents such as aspirin.
Care is advised in the administration of Paracetamol to patients with alcohol dependency, severe renal or severe hepatic impairment.
Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and edema have been reported in association with NSAID therapy.
As with other NSAIDs and combinations, caution is advised in elderly patients who are more likely to have concomitant renal, hepatic or cardiovascular impairment or receiving concurrent medication.
Chlorzoxazone should not be given to patients with impaired liver function and should be discontinued if signs of liver damage appear.
Pregnancy: The drug is not recommended in pregnant women
Lactation: The drug is not recommended in breast-feeding women.

DOSAGE AND DIRECTIONS FOR USE:
Route of administration: Oral
One tablet two-three times daily or as directed by physician.

ADVERSE EFFECTS:
GI disturbances, nephritic syndrome, epigastric pain, nausea, vomiting, diarrhea, hepatitis, rash, pruritus, prolonged bleeding time.

DRUG INTERACTIONS:
Lithium, Digoxin and Methotrexate: Diclofenac sodium may increase plasma concentrations of lithium, Digoxin and Methotrexate
Ciclosporin and tacrolimus: Cases of nephrotoxicity have been reported in patients receiving concomitant ciclosporin and NSAIDs, including diclofenac sodium.
Antihypertensive: Concomitant use of NSAIDs with antihypertensive drugs (i.e. beta-blockers, angiotensin converting enzyme (ACE) inhibitors, diuretics) may cause a decrease in their antihypertensive effect via inhibition of vasodilatory prostaglandin synthesis.
The risk of Paracetamol toxicity may be increased in patients receiving other potentially heatotoxic drugs or drugs that induce hepatic microsomal enzymes. Coadministration of Paracetamol with rifampicin, isoniazid, chloramphenicol, antiepileptic drugs and antiviral drugs is to be avoided.
Metoclopromide may increase the absorption of Paracetamol whereas excretion and plasma concentration may be altered when coadministered with probenecid.
Cholestyramine also reduces the absorption of Paracetamol.
The concomitant use of chlorzoxazone with alcohol or other CNS depressant may have an additive effect.

OVERDOSAGE:
May Cause severe hepatotoxicity on acute over dose.
Overdose may cause headache, nausea, vomiting, abdominal pain, dizziness, hepatic failure and acute renal failure.
Treatment, if required, includes gastric lavage, activated charcoal, and other symptomatic measures as per medical advice.

PRESENTATION:
Blister Pack

STORAGE INSTRUCTIONS:
Do not store above 30°C. Protect from light.

Manufactured by :
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