SKAMREX TABLETS

(Paracetamol 450 mg + Orphenadrine Citrate 35 mg)

COMPOSITION

Each tablet contains Paracetamol 450 mg and Orphenadrine Citrate 35 mg.

DESCRIPTION AND PHARMACOLOGY

Skamrex combines paracetamol, an analgesic and antipyretic, with orphenadrine citrate, a centrally acting skeletal muscle relaxant with anticholinergic properties. The combination provides symptomatic relief of pain associated with muscle spasm.

INDICATIONS

For symptomatic relief of painful musculoskeletal conditions associated with muscle spasm, including sprains, strains, acute torticollis, whiplash injuries and tension or occipital headache associated with neck muscle spasm.

DOSAGE AND ADMINISTRATION

For oral use. Adults: the reference product recommends two tablets three times daily, as prescribed by a physician. Do not exceed the prescribed dose. Use the lowest effective dose for the shortest necessary duration. Not recommended for children without specific medical advice. Do not combine with other paracetamol-containing medicines.

CONTRAINDICATIONS

Hypersensitivity to paracetamol, orphenadrine or formulation ingredients; glaucoma; prostatic enlargement or bladder-neck obstruction; myasthenia gravis; oesophageal spasm or pyloric/duodenal obstruction. Avoid use in severe hepatic impairment unless specifically directed by a specialist.

WARNINGS AND PRECAUTIONS

Excess paracetamol can cause severe, potentially fatal liver injury, even when early symptoms are mild. Seek urgent medical help after suspected overdose. Use cautiously in hepatic or renal impairment, heavy alcohol use, dehydration, elderly patients, urinary retention, tachycardia, cardiac arrhythmias or coronary disease. Orphenadrine can cause drowsiness, dizziness, blurred vision and impaired alertness; avoid driving or operating machinery until effects are known. Anticholinergic effects may be increased in susceptible patients.

DRUG INTERACTIONS

Alcohol and other sedating medicines may increase central nervous system impairment. Other anticholinergic drugs may intensify dry mouth, constipation, blurred vision or urinary retention. Prolonged regular paracetamol use may increase the anticoagulant effect of warfarin; monitor INR as appropriate. Ask a physician or pharmacist before combining with other medicines.

PREGNANCY AND LACTATION

Use during pregnancy only when clearly necessary following medical assessment. Information on the combination during breastfeeding is limited; seek professional advice before use.

ADVERSE REACTIONS

Possible effects include dry mouth, nausea, dizziness, drowsiness, blurred vision, constipation, palpitations and difficulty passing urine. Allergic reactions, severe skin reactions and liver injury are uncommon but potentially serious. Stop treatment and obtain medical help for rash with blistering, breathing difficulty, severe confusion or signs of liver injury.

OVERDOSAGE

Urgent hospital assessment is required after suspected overdose, even if the patient initially feels well. Paracetamol overdose can cause delayed hepatic injury and requires prompt evaluation for acetylcysteine treatment. Orphenadrine overdose may cause agitation, confusion, hallucinations, rapid heart rate, seizures or arrhythmias. Treatment is supportive and directed by clinicians.

STORAGE

Store in a cool, dry place, protected from heat, light and moisture. Keep out of reach of children. Follow the storage conditions printed on the approved outer pack.

PRESENTATION

Skamrex Tablets 450 mg + 35 mg. Pack of 10 x 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.