ORPHENAMOL TABLETS

DESCRIPTION:
A white, round, biconvex tablet, scored on one side and plain on the other.

COMPOSITION:
Each tablet contains 35 mg Orphenadrine Citrate BP and 450 mg Paracetamol BP.

PPHARMACODYNAMICS
Orphenadrine is a skeletal muscle relaxant. Paracetamol is an analgesic and antipyretic.

PHARMACOKINETICS:
Orphenadrine is readily absorbed from the gastrointestinal tract and is almost completely metabolised to at least eight metabolites. Orphenadrine and its metabolites are excreted from the body in the urine, with a half life of 14 hours.

Paracetamol is also readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. Paracetamol is distributed into most body tissues. It has a half life of between 1 to 3 hours.

INDICATIONS:
Tension headache, occipital headaches associated with spasm of skeletal muscles in the region of the head and neck. Acute and traumatic conditions of the limbs and trunk: sprains, strains, whiplash injuries, acute torticollis, prolapsed intervertebral disc.

WARNING AND PRECAUTIONS:
Should be used with caution in patient with glaucoma, tachycardia and urinary retention. This preparation contains PARACETAMOL. Do not take any other PARACETAMOL containing medicines at the same time.
Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash.
These could be signs of serious condition. If these reactions occur, stop use and seek medical assistance right away.

INTERACTIONS WITH OTHER MEDICAMENTS:
Increased paracetamol absorption with metoclopramide and domperidone. Decreased paracetamol absorption with cholestyramine. May increase risk of bleeding with warfarin and coumarins. Increased anticholinergic side effects with other anticholinergic drugs. Additive CNS effects with propoxyphene. Increased bupropion levels with concurrent use. May antagonise actions of centrally acting anticholinesterases e.g. donepezil, galantamine, rivastigmine, tacrine. May decrease levodopa absorption with concurrent use.
Potentially Fatal: Increased risk of liver damage with alcohol.

PREGNANCY AND LACTATION:
Not recommended for use during pregnancy. Not be taken during lactation as orphenadrine and paracetamol are excreted into breast milk.

ADVERSE REACTIONS:
Within the recommended dosage, undesirable side effects are seldom experienced. Dry mouth, blurred vision, nausea or dizziness may, however, occur.
Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/ Toxic Epidermal Necrolysis have been reported.

CONTRAINDICATIONS:
Glaucoma, urinary retention and myasthenia gravis. Not recommended for children under 12 years.

DOSAGE AND ADMINISTRATION:
Up to 2 tablets taken orally three times daily.

ROUTE OF ADMINISTRATION:
Oral administration

OVERDOSAGE:

Symptoms:	Symptoms of orphenadrine overdosage are excitement, confusion, delirium leading to coma.Convulsions and tachycardia with dilated pupils and urinary retention may occur. Paracetamol overdosage may cause acute liver damage by symptoms may not appear for up to several days after ingestion.
Treatment	Gastric lavage should be carried out immediately, regardless of the estimated ingested dose. Convulsions and delirium respond to relatively large doses of diazepam, preferably by mouth. Adequate hydration of the patient is important. It is recommended that the patient be referred to a hospital where early and regular monitoring of plasma paracetamol levels can be carried out. If instituted sufficiently early, treatment with N-acetylcysteine, L-methionine or cysteamine will minimise liver damage.

EFFECTS ON ABILIY TO DRIVE AND USE MACHINE:
May affect ability to drive or operate machinery.

STORAGE CONDITIONS :
Store below 30°C Protect from light.

PRESENTATION
Blisters of 10 tablets. Box of 30, 60, 90 or 1000 tablets.

MANUFACTURED BY:
NORIPHARMA SDN. BHD. 200701034604 (792633-A)
Lot 5030, Jalan Teratai,
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