C E T A G E S I C Tablet

DESCRIPTION:
An oblong, scored tablet, green in color with markings 'dp 500' and 'duo / duo'.

COMPOSITION:
Each tablet contains:
Paracetamol …… 500 mg
Orphenadrine Citrate…….. 25 mg

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

PHARMACOKINETIC:
Orphenadrine is readily absorbed from the gastrointestinal tract and is almost completely metabolized to at least 8 metabolites. It is mainly excreted in the urine as metabolites and small amounts of unchanged drug.

Paracetamol is readily absorbed from the gastro intestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. The elimination half-life of paracetamol varies from about 1 to 3 hours.

Paracetamol is metabolized predominantly in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. A minor hydroxylated metabolite (*N*-acetyl-*p*-benzoquinoneimine) which is usually produced in very small amounts by mixed-function oxidases in the liver and kidney and which is usually detoxified by conjugation with glutathione may accumulate following paracetamol overdosage and cause tissue damage.

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.

RECOMMENDED DOSAGE: Two tablets three times daily.

ROUTE OF ADMINISTRATION: To be taken orally only**.**

CONTRAINDICATIONS:
Orphenadrine shows some anticholinergic activity and should not be used in patients with glaucoma, prostatic hypertrophy or obstruction at the bladder neck or myasthenia gravis.

WARNINGS AND PRECAUTIONS:
Orphenadrine may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; ambulatory patients should therefore be cautioned accordingly. Orphenadrine should be used with caution in patients with tachycardia, cardiac decompensation, coronary insufficiency, cardiac arrhythmias.
Safety of continuous long-term therapy with orphenadrine has not been established. Therefore, if orphenadrine is prescribed for prolonged use periodic monitoring of blood, urine and liver function values is recommended.
Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these conditions occur, stop use and seek medical assistance right away.

> This preparation contains PARACETAMOL. Do not take any other PARACETAMOL containing medicines at the same time.

INTERACTIONS WITH OTHER MEDICAMENTS:
Metabolism/Transport Effects: Refer to individual components
Avoid Concomitant Use: *Avoid concomitant use of Orphenadrine and Paracetamol with any of the following:* Acidinium; Alcohol (Ethyl);Azelastine (Nasal);Cimetropium; CNS Depressants; Eluxadoline ; Glucagon; Glycopyrrolate Glycopyrrolate (Oral Inhalation); Ipratropium (Oral Inhalation);Levosulpiride; Paraldehyde ; Potassium Chloride; Thalidomide; Tiotropium:Umeclidinium
Increased Effect/Toxicity: *Orphenadrine and Paracetamol may increase the levels/effect of* Abobotulinumtoxin A; Anticholinergic Agents: Azelastine (Nasal) ; Cimetropium; Eluxadoline; Glucagon, Glycopyrrolate Glycopyrrolate (Oral Inhalation) Metyrosine, Mirabegron, OnabotulinumtoxinA, Paraldehyde, Potassium Chloride, Pramipexole, Ramosetron, RimabotulinumtoxinB, ROPINRole, Rotigotine, Selective Serotonin Reuptake Inhibitors, Titalidomide, Thiazide and Thiazide-Like Diuretics; tiotropium
The levels/effects of Orphenadrine and Paracetamol may be increased by: Acidinium; Alcohol (Ethyl);Brimonidine (Topical), Cannabis; CNS Depressants; Dronabinol Ipratropium (Oral Inhalation); Kava Kava, Magnesium Sulfate, Minocycline,Nabilone, Pramlintide, Rufinamide, Tetrahydrocannabinol, Umeclidinium
Decreased Effect: *Orphenadrine and Paracetamol may decrease the levels/effect of:* Acetylcholinesterase Inhibitors, Gastrointestinal Agents (Prokinetic), Itopride, Levosulpiride Secretin
The levels/effects of Orphenadrine and Paracetamol may be decreased by: Acetylcholinesterase Inhibitors

Use in pregnancy:
ADVERSE EFFECTS:
Side effects rarely occur at the recommended dosage. Those encountered are associated with anticholinergic activity and may include nausea, dry mouth, blurring of vision. Rarely, rash or drowsiness may occur. These symptoms disappear rapidly with a reduction in dosage or cessation of medication. No toxic effects have been observed. Additionally. Cutaneous hypersensitivity reactions including skin rashes, angioedema, Steven Johnson Syndrome/ Toxic Epidermal Necrolysis have been reported.

OVERDOSE AND TREATMENT:
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 but 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, 1-methionine or 1-cysteamine will minimize liver damage.

STORAGE CONDITIONS: Store below 30°C. Protect from light. Keep out of reach of children. *Jauhkan daripada kanak-kanak*.

SHELF LIFE: Please refer to outer package.

PACKING/PACK SIZES: Bottles of 120's. in PE bottles with presence of dessicant

PRODUCT REGISTRATION HOLDER & MANUFACTURER:
DUOPHARMA (M) SDN BHD
Lot 2599 Jalan Seruling 59 Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor, MALAYSIA

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