

MEDIGESIC

COMPOSITION:

Medigesic Tablets

Each tablet contains:

Orphenadrine Citrate(B.P)..... 35mg

Paracetamol (B.P)..... 450mg

Product conforms to the Manufacturer 's Specifications.

Medigesic Forte Tablets

Each tablet contains:

Orphenadrine Citrate (B.P) 50mg

Paracetamol (B.P) 450mg

Caffeine (B.P) 30mg

Product conforms to the Manufacturer's Specifications.

Medigesic-C Tablets

Each tablet contains:

Orphenadrine Citrate (B.P) 35mg

Paracetamol (B.P)..... 400mg

Caffeine (B.P) 60mg

Product conforms to the Manufacturer's Specifications.

DESCRIPTION:

Orphenadrine Citrate (Ethanamine, N,N-dimethyl-2-[(2- methylphenyl) phenylmethoxy]-citrate) is a white crystalline powder having a bitter taste. It is practically odorless, sparingly soluble in water and slightly soluble in alcohol. The molecular formula is $C_{18}H_{23}NO \cdot C_6H_8O_7$ and the molecular weight is 461.50. Orphenadrine is a skeletal muscle relaxant. It works by helping to decrease pain, which helps muscles to relax.

Paracetamol (4'-hydroxyacetanilide) is a slightly bitter, white, odorless, crystalline powder, is a non-opiate, non-salicylate analgesic and antipyretic. The molecular formula is $C_8H_9NO_2$ and the molecular weight is 151.16.. Paracetamol is an analgesic and antipyretic. Paracetamol has a highly targeted action in the brain, it blocks an enzyme involved in the transmission of pain.

Caffeine (1,3,7-trimethylxanthine) is a bitter, white powder or white-glistening needles, is a central nervous system stimulant. The molecular formula is $C_8H_{10}N_4O_2$ and the molecular weight is 194.19. Caffeine is a central nervous system stimulant. It works by stimulating the brain. It acts through adenosine receptors and monoamine neurotransmitters. It is an adenosine receptor antagonist and adenosine 3',5'-cyclic monophosphate (cAMP) phosphodiesterase inhibitor.

PHARMACOKINETICS:

Orphenadrine Citrate: Orphenadrine is readily absorbed from the gastrointestinal tract and is almost completely metabolized. Peak plasma levels occur 2 hrs after oral administration. Duration of action is about 4-6 hrs in the recommended dose. The half life is approximately 14 hrs for the parent drug and 2-25 hrs for metabolites. Excretion is via urine and faeces. Most of Orphenadrine is degraded to 8 known metabolites. 8% is excreted unchanged in urine.

Paracetamol: Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10-60 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



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negligible at usual therapeutic concentrations but increases with increasing concentrations. The elimination half life of Paracetamol varies from about 1-3 hrs. Paracetamol is metabolized predominantly in the liver and excreted in the urine mainly as the glucuronide and sulfate conjugates. Less than 5% is excreted as unchanged Paracetamol.

Caffeine: Caffeine is readily absorbed after oral administration. The peak plasma level for Caffeine range from 6-10mg/L and the mean time to reach peak concentration ranged from 30 minutes to 2 hours. The volume of distribution in infants and adults is 0.8-0.9 L/kg and 0.6 L/kg respectively. Protein binding is low 25-36%. Hepatic cytochrome P450 1A2 (CYP 1A2) is involved in Caffeine biotransformation. About 80% of a dose of Caffeine is metabolized to paraxanthine (1,7-dimethylxanthine), 10% to theobromine (3,7-dimethylxanthine) and 4% to theophylline (1,3-dimethylxanthine). The half life is 3 to 7 hours in adults and 65 to 130 hours in neonates. In young infants, the elimination of Caffeine is much slower than that in adults due to immature hepatic and/or renal function.

INDICATIONS:

Symptomatic relief of mild to moderate pain of acute musculoskeletal disorders. For the relief of discomfort associated with acute painful musculoskeletal conditions and for the relief of painful skeletal muscle spasm associated with muscle injury, surgery, sprains and strains, low-back pain, prolapsed intervertebral disc, fractures before and after reduction and immobilization and acute torticollis.

DOSAGE & ADMINISTRATION:

Adults: 1 tablet three times daily or as directed by physician.

CONTRAINDICATIONS:

The drug is contraindicated in patients who have demonstrated previous hypersensitivity to the drug. Because of the mild anticholinergic effects of Orphenadrine, this product should not be used in patients with glaucoma, pyloric or duodenal obstruction, achalasia, prostatic hypertrophy or obstructions of the bladder neck. Orphenadrine Citrate, Paracetamol and Caffeine tablets are also contraindicated in patients with myasthenia gravis and in patients known to be sensitive to Acetaminophen and Caffeine.

WARNINGS:

Orphenadrine Citrate, Acetaminophen and Caffeine tablets may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle.

PRECAUTIONS:

Safety of continuous long term therapy with Orphenadrine Citrate, Acetaminophen and Caffeine tablets has not been established therefore, if Orphenadrine Citrate, Acetaminophen and Caffeine tablets are prescribed for prolonged use, periodic monitoring of blood, urine and liver function values are recommended.

PREGNANCY AND LACTATION:

Since safety of the use of this preparation in pregnancy, during lactation or in the childbearing age has not been established, use of the drug in such patients requires that the potential benefits of the drug be weighed against its possible hazard to the mother and child.



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DRUG-DRUG INTERACTIONS:

Due to the potential for Acetaminophen hepatotoxicity at doses higher than the recommended dose, Orphenadrine Citrate, Acetaminophen and Caffeine should not be used concomitantly with other Acetaminophen containing products. Confusion, anxiety and tremors have been reported in a few patients receiving Propoxyphene and Orphenadrine concomitantly. As these symptoms may be simply due to an additive effect, reduction of dosage and/or discontinuation of one or both agents is recommended in such cases.

ADVERSE DRUG REACTIONS:

Adverse effects of Orphenadrine Citrate, Acetaminophen and Caffeine tablets are those seen with Acetaminophen and Caffeine or those usually associated with mild anticholinergic agents. These may include tachycardia, palpitation, urinary hesitancy or retention, dry mouth, blurred vision, dilatation of the pupil, increased intraocular tension, weakness, nausea, vomiting, headache, dizziness, constipation, drowsiness and rarely urticaria and other dermatoses. These adverse reactions can usually be eliminated by reduction in dosage.

OVERDOSAGE:

Orphenadrine Citrate: Known symptoms of overdose with Orphenadrine include tachycardia, excitement, confusion and delirium leading to coma. Convulsions, dilated pupils and urinary retention may occur. Adequate hydration of the patient is important.

Paracetamol: Overdosage with Paracetamol may cause hepatic cytolysis which can lead to hepatocellular insufficiency, metabolic acidosis, encephalopathy, coma and death. Nausea, vomiting, anorexia, pallor and abdominal pain generally appear during the first 24 hours of overdosage with Paracetamol. Immediate medical management is required in the event of overdose.

Caffeine: Signs and symptoms reported after Caffeine overdose include fever, tachypnea, insomnia, fine tremor of the extremities, hypertonia, tonic-clonic movements, vomiting, hyperglycemia and elevated blood urea nitrogen. Seizures have also been reported in cases of overdose.

Treatment of Caffeine overdose is primarily symptomatic and supportive.

INSTRUCTIONS:

Store in a cool & dry place below 25°C.
Protect from light, heat and moisture.
Keep out of reach of children.

ACTIVE CONSTITUENTS:

Dibona tablets is a formulation of
Vitamin B6.....100mg

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Vitamin B6.....100mg



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PRESENTATION:

Medigesic tablets are available in blister pack of 30's.

Medigesic tablets are available in blister pack of 60's.

Medigesic Forte tablets are available in blister pack of 10's.

Medigesic Forte tablets are available in blister pack of 30's.

Medigesic Forte tablets are available in blister pack of 60's.

Medigesic Forte tablets are available in blister pack of 100's.

Medigesic-C tablets are available in blister pack of 30's.



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