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Flexpro Extra

Film Coated Tablets

Methocarbamol and Paracetamol

Muscle Relaxant, Analgesic, Antipyretic

Composition:

Each film coated tabletcontains: Methocarbamol 400 mg + Paracetamol 500 mg

Inactives: Povidone ,croscarmellose sodium, cellulose, magnesium stearate , hydroxypropyl methyl cellulose, talc, titanium dioxide and polyethyleneglycol

Clinical Pharmacology:

Methocarbamol, a carbamate derivative of guaifenesin, is a central nervous system depressant with sedative and musculoskeletal relaxant properties. It has no direct action on the contractile mechanism of striated muscles, the motor end plate or the nerve fiber. The halflifeof methocarbamol is about 1- 2 hours.

Paracetamol is a non-opioid analgesic and an antipyretic. The analgesic effect of Paracetamol is thought to be due to the inhibition of prostaglandin synthesis in the central nervous system and the periphery, and by elevation of pain threshold.

The antipyretic effect is due to a central action on the hypothalamic heat regulating centre to produce peripheral vasodilatation and subsequent heat loss.

The plasma half-life of paracetamol is approximately 1 to 3 hours.

The combination of Methocarbamol with Paracetamol produces greater analgesia than that produced by either agent administered alone.

Pharmacokinetics:

In healthy volunteers, the plasma clearance of methocarbamol ranges from 0.20to 0.80 L/h/kg; the mean plasma elimination half-life ranges from 1 to 2 hours, and the plasma protein binding ranges from 46% to 50%.

Methocarbamol is metabolized via dealkylation and hydroxylation. Conjugation of methocarbamol is also likely. Essentially all methocarbamol metabolites areeliminated in the urine. Small amounts of unchanged methocarbamol are excreted in the urine.

Paracetamol is 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. Plasma protein binding is negligible at usual therapeutic doses butincreaseswith increasing doses. The elimination half-life varies from about 1 to 3 hours.

Paracetamol is metabolised extensively in the liver and excreted in the urine mainly as inactive glucuronide and sulfate conjugates. Less than 5% is excreted unchanged.

The metabolites of paracetamol include a minor hydroxylated intermediate which has hepatotoxic activity. This intermediate metabolite is detoxified by conjugation with glutathione; however, it can accumulate following paracetamol over dosage (more than 150mg/kg or 10g total paracetamol ingested) and if left untreated can cause irreversible liver damage.

Indications:

Flexpro Extra provides dual actions (Centrally acting muscle relaxant and analgesic) to management of spasm and pain associated with acute painful musculoskeletal conditions; acute torticollis, acute low back pain, bursitis, acute myositis, whiplash injury and acute muscle sprains or strains.

Dosage and Administration:

Adults & Children over 12 years:

- Mild to Moderate cases: One tablet 3 times daily.
- Severe Cases: 2 tablets 3 times daily.
- Do not use more than 21 days except after your physician's consultation.

Contraindications:

* Concurrent use of alcohol.
* Concurrent use of other paracetamol containing products.
* Known hypersensitivity to either Methocaramol or Paracetamol.

Adverse Reactions:

The mostcommonly reported adverse reactionsare dizziness, drowsiness, sedation, nausea, gastricupsetand vomiting.

Other less frequent to rarely reported adverse reactions are minorvisual disturbances, skin rashes or nasal congestion.

Paracetamol toxicity may cause liver damage.

Drug Interactions:

*** CNS Depressants including Alcohol:** Methocarbamol in combination with alcohol, tranquilizers, sedatives, hypnotics, and other central nervous system depressants has additive depressanteffects, and the patientshould be so advised.

*** Pyridostigmine bromide:** Methocarbamol may inhibit the effect of pyridostigmine bromide. Therefore, Methocarbamol should be used with caution in patientswith myasthenia gravis receiving anticholinesterase agents.

*** Warfarin:** Paracetamol may affect prothrombin time in patients receiving anticoagulant therapy. Warfarin dosage adjustments may be required.

*** Chloramphenicol:** Concurrent administration of paracetamol and chloramphenicol may increase chloramphenicol serum concentrations.

*** Zidovudine:** Concurrent administration of Paracetamol and Zidovudine has been associated with an increase of neutropenia, especially during chronic therapy.

Pregnancyand Lactation:

Teratogenic Effects - Pregnancy Category C:

Should not be used during pregnancy & lactation.

Pediatric Use:

Safety and effectiveness of **Flexpro Extra** in pediatric patients below the age of 12 have not been established.

Warning and Precautions:

* **Flexpro Extra** must be used underphysician's supervision.

* Methocarbamol may possess a general CNS depressant effect; patients receiving **Flexpro Extra** should be cautioned about combined effects with alcohol or other CNS depressants.

*** Use in activities requiring mental alertness:** Methocarbamol may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery ordriving a motor vehicle.

*** Use in Patients with Hepatic or Renal Impairment:** Methocarbamol should be administered with caution to patients with renal or hepatic impairmentsince higherserum concentration ordelayed elimination may occur.

Package and Storage:

Box containing 2 blister packs each of 10 tablets.

Store below 30 ^{o} C, protected from light and moisture.

Instructions to Patients:

* Keep this medicine and all medicines away from children.

Productof :

Medical Union Pharmaceuticals,

Abu-Sultan, Ismailia, Egypt.

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