Colimax™

Colchicine

COMPOSITION

Colimax™ 0.6 tablet: Each film coated tablet contains Colchicine USP 0.6 mg.

PHARMACOLOGY

An acute attack of gout apparently occurs as a result of an inflammatory reaction to crystals of monosodium urate that are deposited in the joint tissue from hyperuric body fluids; the reaction is aggravated as more urate crystals accumulate. Leukocytes migrate to the sites where urate crystals have been deposited and try to engulf the crystals by phagocytosis. As a result lactic acid and proinflammatory enzymes are released which cause inflammation with severe pain, redness, and swelling of the affected joint. Lactic acid favors a local decrease in pH that enhances uric acid deposition. Colchicine inhibits the phagocytosis of uric acid by leukocytes & also diminishes the lactic acid production directly. Thus interrupts the cycle of urate crystal deposition and inflammatory response that sustains the acute attack of gout.

Colchicine is absorbed when given orally, reaching a mean Cmax of 2.5 ng/mL (range 1.1 to 4.4 ng/mL) in 1 to 2 hours after a single dose administered under fasting conditions. The mean apparent volume of distribution is approximately 5 to 8 L/kg. Colchicine binding to serum protein is low (39 ± 5%), primarily to albumin regardless of concentration. CYP3A4 is involved in the metabolism of Colchicine to 2-O-demethylcolchicine and 3-O-demethylcolchicine. Plasma levels of these metabolites are minimal (less than 5% of parent drug). Following multiple oral doses (0.6 mg twice daily), the mean elimination half-life is 26.6 to 31.2 hours.

INDICATION

Prophylaxis of gout flares and treatment of acute gout attack in adults.

DOSAGE AND ADMINISTRATION

Prophylaxis of Gout Flares:

0.6 mg (1 tablet) once or twice daily in adults and adolescents older than 16 years of age. Maximum dose 1.2 mg/day (2 tablets).

Treatment of Acute Gout:

- 1.2 mg (2 tablets) at the first sign of a gout flare followed by 0.6 mg (1 tablet) one hour later is effective when prescribed within 12 hours of onset of an acute gout attack.
- The maximum recommended dose for treatment of acute gout attack is 1.8 mg over a 1 hour period. The prophylactic dose should be resumed after 12 hours of the course.

Colchicine tablets are administered orally, without regard to meals.

SIDE EFFECT

Blood dyscrasias: Myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, and aplastic anemia have been reported.

Diarrhea and pharyngolaryngeal pain may occur.

CONTRAINDICATION

Patients with renal or hepatic impairment should not be given Colchicine in conjunction with Permeability glycoprotein (P-gp) or strong CYP3A4 inhibitors (e.g., clarithromycin or cyclosporine).

DRUG INTERACTION

Co-administration of P-gp and/or CYP3A4 inhibitors (e.g., clarithromycin or cyclosporine) have been demonstrated to alter the concentration of Colchicine.

USE IN PREGNANCY & LACTATION

Pregnancy Category C: There are no adequate and well-controlled studies with Colchicine in pregnant women.

Nursing Mothers: Colchicine is excreted into human milk. Caution should be exercised when administered to a nursing woman.

USE IN CHILDREN

Gout is rare in pediatric patients. Safety and effectiveness of Colchicine in pediatric patients have not been established.

OVERDOSAGE

The exact dose of colchicine that produces significant toxicity is unknown. Fatalities have occurred after ingestion of a dose as low as 7 mg over a 4-day period, while other patients have survived after ingesting more than 60 mg. A review of 150 patients who overdosed on colchicine found that those who ingested less than 0.5 mg/kg survived and tended to have milder toxicities, such as gastrointestinal symptoms, whereas those who took 0.5 to 0.8 mg/kg had more severe reactions, such as myelosuppression.

STORAGE CONDITION

Store below 30°C temperature. Protect from light and moisture. Keep the medicine out of reach of children.

HOW SUPPLIED

Colimax 0.6 tablet: Each box contains 30 tablets in Alu-PVC blister pack.

Manufactured by:

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

2000008309

TM-Trade Mark.