Colimax[™]

Colchicine USP 0.6 mg

Active Ingredient Colchicine USP 0.6 mg

Indication

Colchicine is approved by US FDA for the prevention & treatment of acute gout attack.

Dosage & Administration

Prophylaxis of gout flare:

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

Treatment of acute gout attack:

• 1.2 mg (2 tablets) at first sign of a gout flare followed by 0.6 mg (1 Tablet) one hour later.

• The maximum recommended dose for treatment of acute gout attack is 1.8 mg over a 1 hour period.

• The maintenance dose will be as same as the prophylactic dose, which should be resumed after 12 hours of the acute treatment course.

Contraindication: Patients with renal or hepatic impairment should not be given Colchicine in Conjunction with permeable glycoprotein or strong CYP3A4 inhibitors (ex.: Clarithromycin or Cyclosporine)

Side Effect

Myelosuppression, leucopenia, granulocytopenia, thrombocytopenia & aplastic anemia have been reported. Diarrhea & pharyngolaryngeal pain may occur.

Drug Interaction

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

Use in Pregnancy & Lactation

Pregnancy Category C. There are no adequate & well-controlled studies in pregnant women. 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 & effectiveness of Colchicine in pediatric patients have not been established. Patient less than 16 years of age is not recommended

Preparation 0.6 mg Tablet.

Manufactured by

