

Duric®

Allopurinol

Description: Duric® contains Allopurinol BP which is xanthine oxidase inhibitor and is an effective drug for the therapy of hyperuricemia.

Mode of action: In contrast with the uricosuric agents that increase the renal excretion of urate, allopurinol inhibits the terminal steps in uric acid biosynthesis. In man, uric acid is formed by the xanthine oxidase catalyzed oxidation of hypoxanthine and xanthine. Allopurinol decreases the production of uric acid by inhibiting xanthine oxidase.

Pharmacokinetics: It is rapidly and well absorbed from the intestine. Its plasma half life is about 1 hour. It is largely converted to oxypurinol which itself is a weak xanthine oxidase inhibitor. They are not bound to serum proteins and are excreted mainly in urine.

Composition

Duric® 100 mg Tablet: Each tablet contains 100 mg Allopurinol BP.

Duric® 300 mg Tablet: Each tablet contains 300 mg Allopurinol BP.

Indications: Duric® (allopurinol) is used as long-term medication to treat hyperuricemia and its complications. It alone or in combination with uricosurics is particularly indicated in

- (a) Gout uncontrolled by uricosurics
- (b) Severe tophaceous gout
- (c) Prevention and treatment of renal calculi
- (d) Gout with renal failure
- (e) Acute urate nephropathy
- (f) Gout with high levels of urinary urate
- (g) Intolerance to uricosuric drugs
- (h) Treatment of hyperuricemia associated with leukemia or resulting from radiotherapy or the use of antineoplastic agents.

Dosage & administration

Gout

Initially 100 mg daily as a single dose after food, increased by 100 mg daily at weekly interval until the concentration of uric acid in serum is reduced to 60 mg per ml the average daily dose is 200 to 300 mg for those with mild gout, and 400 to 600 mg for those with moderately severe tophaceous gout. Up to 300 mg may be taken as a single daily dose: large amounts should be taken in divided doses.

Hyperuricemia associated with leukemia or resulting from radiotherapy or the use of antineoplastic agents:

Initial dose is 200 mg thrice daily commencing 2 or 3 days before radiotherapy or the commencement of treatment with antineoplastic agents and adjusted as required to a maintenance dose usually of 300 to 400 mg daily.

Children

Hyperuricemia associated with malignancies:

6-10 years : 300 mg daily.

under 6 years: 150 mg daily.

Patients with impaired renal function: 100-200 mg daily.

Contraindications: Patients who have developed a severe reaction to Allopurinol should not be restarted on the drug.

Side effects: The most common side effect is skin rash, Other side effects include fever, chills, leucopenia, eosinophilia and arthralgia, nausea vomiting, abdominal pain, diarrhea, alopecia, headache, drowsiness and peripheral neuritis.

Use in pregnancy & lactation: There are, however, no adequate or well controlled studies in pregnant women. This drug should be used during pregnancy only if clearly indicated.

Allopurinol has been found in breast milk, caution should be exercised when Allopurinol is administered to a lactating mother.

Precautions: Duric should not be used for the treatment of an acute attack of gout Treatment should be stopped if any skin reaction develops. It should be administered with care to patients with renal or hepatic impairment and doses may need to be reduced. Fluid intake should be much to maintain a urinary output of not less than 2 litres a day.

Drug interactions: Anticoagulant - Allopurinol prolongs the half life of the anticoagulant, dicumarol. Diuretic - Concomitant use of Allopurinol and thiazide diuretics may contribute to the enhancement of Allopurinol toxicity. Cytotoxic agent -Enhanced bone marrow suppression by cyclophosphamide and other cytotoxic agent has been reported among patients with neoplastic disease.

Overdosage: Massive overdosing or acute poisoning by Duric® has not been reported. In mice, the 50% lethal dose (LD50) is 160 mg/kg given intraperitoneally (IP) with deaths delayed up to 5 days and 700 mg/kg orally (PO) (approximately 140 times the usual human dose) with deaths delayed up to 3 days. In rats, the acute LD50 is 750 mg/kg IP and 6000 mg/kg PO (approximately 1200 times the human dose). In the management of overdosage there is no specific antidote for Duric®. There has been no clinical experience in the management of a patient who has taken massive amounts of Duric®. Both Duric® and oxypurinol are dialyzable; however, the usefulness of hemodialysis or peritoneal dialysis in the management of an overdose of Duric® is unknown.

Storage: Store in a cool and dry place, protected from light.

Packaging

Duric® 100 mg Tablet: Each carton contains 10X5 tablets in blister pack.

Duric® 300 mg Tablet: Each carton contains 10X3 tablets in blister pack.



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