

COMPOSITION

Esloric[®] 100 Tablet: Each tablet contains Allopurinol BP 100 mg. Esloric[®] 300 Tablet: Each tablet contains Allopurinol BP 300 mg.

PHARMACOLOGY

Esloric® (Allopurinol) is a xanthine-oxidase inhibitor. Allopurinol and its main metabolite oxipurinol lower the level of uric acid in plasma and urine by inhibition of xanthine oxidase, the enzyme catalyzing the oxidation of hypoxanthine to xanthine and xanthine to uric acid.

INDICATION

Esloric® (Allopurinol) is indicated for reducing urate/uric acid formation in conditions where urate/uric acid deposition has already occurred (e.g. gouty arthritis, skin tophi, nephrolithiasis) or is a predictable clinical risk (e.g. treatment of malignancy potentially leading to acute uric acid nephropathy).

Esloric® (Allopurinol) is indicated for management of 2,8-dihydroxyadenine (2,8-DHA) renal stones related to deficient activity of adenine phosphoribosyltransferase.

Esloric® (Allopurinol) is indicated for the management of recurrent mixed calcium oxalate renal stones in the presence of hyperuricosuria, when fluid, dietary and similar measures have failed.

DOSAGE AND ADMINISTRATION

Dosage in Adults: Allopurinol should be introduced at low dosage e.g. 100mg/day to reduce the risk of adverse reactions and increased only if the serum urate response is unsatisfactory. Extra caution should be exercised if renal function is poor. The following dosage schedules are suggested:

100 to 200 mg daily in mild conditions

300 to 600 mg daily in moderately severe conditions

700 to 900 mg daily in severe conditions

If dosage on a mg/kg body weight basis is required, 2 to 10 mg/kg body weight per day should be used. *Dosage in children:* Children under 15 years: 10 to 20 mg/kg body weight per day up to a maximum of 400 mg daily. *Dosage in renal impairment:* In severe renal insufficiency, it may be advisable to use less than 100 mg /day or to use single doses of 100 mg at longer intervals than one day.

Instructions for Use: Allopurinol may be taken orally once a day after a meal. If the daily dosage exceed 300 mg and gastrointestinal intolerance be

manifested, a divided doses regimen may be appropriate.

CONTRAINDICATION AND PRECAUTION

Allopurinol should not be administered to individuals known to be hypersensitive to this drug.

SIDE EFFECT

The following are some of the side effects that are known to be associated with this medicine: Allergic skin reactions such as rash or itch, sleepiness, vertigo, diarrhoea, constipation, nausea, vomiting or abdominal pain.

DRUG INTERACTION

Allopurinol has interaction with the following drugs or following groups of drugs: 6-mercaptopurine and azathioprine, Vidarabine (Adenine Arabinoside), Salicylates and uricosuric agents, Chlorpropamide, Coumarin anticoagulants, Phenytoin, Theophylline, Ampicillin/Amoxicillin, Cyclophosphamide, doxorubicin, bleomycin, procarbazine, mechloroethamine, Cyclosporin and Didanosine.

USE IN PREGNANCY AND LACTATION

There is inadequate evidence of safety of Allopurinol in human pregnancy, Use in pregnancy only when there is no safer alternative and when the disease itself carries risk for the mother or unborn child. There are no data concerning the effects of Allopurinol or its metabolites on the breast-fed baby.

STORAGE

Store at a cool and dry place protected from light & moisture. Keep out of reach of children.

HOW SUPPLIED

Esloric[®] 100 Tablet: Box containing 100 tablets in blister pack. Esloric[®] 300 Tablet: Box containing 30 tablets in blister pack.

Manufactured by

