100x230mm

Cyclophosphamide for Injection BP

200 mg

COMPOSITION:
Each vial contains:
Cyclophosphamide BP
equivalent to anhydrous
Cyclophosphamide 200 mg

CATEGORY
Cytotoxic alkylating agent.

PHARMACOKINETICS
After oral doses, cyclophosphamide is well absorbed from the gastrointestinal tract with a bioavailability greater than 75%. It is widely distributed in the tissues and crosses the blood-brain barrier. It undergoes activation by the mixed function oxidase systems in the liver. The initial metabolites are 4-hydroxycyclophosphamide and its acyclic tautomer, aldophosphamide, which both undergo further metabolism; aldophosphamide may undergo non-enzymatic conversion to active phosphoramide mustard. Acrolein is also produced and may be responsible for bladder toxicity. Cyclophosphamide is excreted principally in urine, as metabolites and some unchanged drug. It crosses the placenta, and is found in breast milk.

INDICATIONS
Leukaemias, lymphogranulomatosis, lymphosarcoma, reticulum cell sarcoma. Hodgkin`s disease, multiple myeloma, retinoblastoma, carcinoma of the breast, adenocarcinoma of the ovary. Inoperable solid malignancies, Combination with surgery, radiation & other therapeutic measures. Minimal change nephrotic syndrome in children.

DOSAGE & ADMINISTRATION
Malignancy : I.V.: 40-50 mg/kg in divided doses over 2-5 days or 10-15mg/kg every 7-10 days or 3-5mg/kg twice weekly.

Directions: Dissolve the contents in 10 ml of Sterile Water for Injection USP and shake until dissolved. The solution should be used immediately after preparation and is usually injected by Intravenous route.

CONTRAINDICATIONS
Bladder haemorrhage, acute urinary tract infection, myelosuppression.
Cyclophosphamide is contraindicated in patients who have demonstrated a previous hypersensitivity to it.

ADVERSE EFFECTS
Nausea, vomiting, visual blurring, facial burning with I.V. administration, teratogenic effect, haemorrhagic cystitis, bone marrow depression, hyponatraemia, sterility, inappropriate secretion of ADH . Alopecia and increased skin pigmentation.

INTERACTIONS
Chloramphenicol: Decreased efficacy of cyclophosphamide due to increase in half-life and decrease in metabolite concentration, increased risk of bone marrow toxicity.
Thiazide diuretics: Increased efficacy, anti-neoplastic induced leukopoenia may be prolonged.
Anticoagulants: Increase in anticoagulant effect.
Digoxin: Decreased serum levels of digoxin.
Doxorubicin: Doxorubicin induced cardiac toxicity potentiated.
Succinylcholine: Neuromuscular blockade prolonged.
Allopurinol: Increased risk of bone marrow toxicity.
Phenobarbitone: Increased metabolism and leukopenic activity.
Myelotoxic drugs, Radiotherapy: Serious toxicity

WARNINGS AND PRECAUTIONS
Diabetes, elderly, hepatic, cardiac or renal impairment, acute systemic or urinary infections. To stop the drug if leucocyte count is less than 3000/cu.mm . Carcinogenic potential, infection, adequate contraception, previous X- Ray or cytotoxic therapy.

STORAGE
Store below 25°C. Protect from moisture.
Avoid long exposure to temperatures above 30°C, to prevent possible sintering or formation of lumps.
Keep out of reach of children.

PRESENTATION
Each 20ml vial containing 200mg powder packed in a printed box..

Manufactured by:
KWALITY PHARMACEUTICALS LTD.
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Tehsil - Nurpur,
Distt.- Kangra, (H.P.) - 176201. INDIA