100 x 240 mm

For the use of Cancer Hospital, Institution of Cancer Specialist Only.

Hydroxyurea Capsules IP 500 mg

AMERICAN

HYDRONCO 500

हाइड्रोको 500 Capsules

COMPOSITION :
Each hard gelatin capsule contains:
Hydroxyurea IP 500 mg
Excipients q.s.
Approved colour used in empty capsule shell.

GENERAL INFORMATION
Hydroxyurea is an antineoplastic that may cause inhibition of DNA synthesis by acting as a ribonucleotide reductase inhibitor.

PHARMACOKINETICS
Hydroxyurea is readily absorbed from the gastrointestinal tract and distributed throughout the body. Peak plasma concentrations are reached within 2 hours. Up to 50% of a dose is metabolised by the liver; Hydroxyurea is excreted in urine as metabolites and unchanged drug. Some is excreted as carbon dioxide via the lungs. About 80% of a dose is reported to be excreted in the urine within 12 hours. Hydroxyurea crosses the blood-brain barrier and the placenta, and is distributed into breast milk.

INDICATIONS
It is S-phase specific. Hydroxyurea is used in the treatment of chronic myeloid leukaemia, and may be used in the myeloproliferative disorders polycythaemia vera and primary (essential) thrombocythaemia. It has also been tried, often combined with radiotherapy, in some solid malignancies. Hydroxyurea has also produced benefit in the haemoglobinopathies, particularly in sickle-cell disease.

DOSAGE AND ADMINISTRATION
- In the treatment of chronic myeloid leukaemia and solid tumours, Hydroxyurea is given by mouth, typically in a single dose of 20 to 30 mg/kg daily or in a single dose of 80 mg/kg every third day. Generally, the continuous regimen is used for chronic myeloid leukaemia, and the intermittent regimen for solid tumours. When used with radiotherapy, Hydroxyurea is started 7 days before radiotherapy. If a beneficial effect is evident after 6 weeks, therapy may be continued indefinitely.
- In essential thrombocythaemia, the initial dose of Hydroxyurea is about 15 mg/kg daily; starting doses of 15 to 20 mg/kg daily are recommended for polycythaemia vera. Doses are subsequently adjusted according to platelet counts.
- In sickle-cell disease initial doses of 15 mg/kg daily are suggested, increased if necessary by 5 mg/kg daily every 12 weeks according to response and blood counts, up to a maximum of 35 mg/kg daily. The BNFC recommends 10 to 20 mg/kg once daily initially for children aged from 1 to 18 years; increments thereafter are similar to those for adults.

CONTRAINDICATIONS
Severe anaemia, marked bone marrow depression.

ADVERSE EFFECTS
Nausea, vomiting, rash, bone marrow depression is the major toxic effect. Alopecia, stomatitis, dysuria. Inflammation & increased pigmentation may occur in areas exposed to radiation. Rare neurological disturbances.

SPECIAL PRECAUTIONS
Monitor hepatic and renal functions. Haematological monitoring (including bone marrow).
Premenopausal women, recent
x-ray or cytotoxic therapy.
Pregnancy : Contraindicated.
Breast feeding : Use with caution.

INTERACTIONS
Lab tests: May cause increase in serum uric acid, creatinine and BUN levels.

STORAGE
Store at a temperature not exceeding 30°C. Protect from light & moisture.

PRESENTATION
Blister strip of 10 capsules and 10 strips are packed in a printed carton.

Marketed by:
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