INJECTION

DARBAZINE 200mg

U.S.P Specs.
(Dacarbazine U.S.P)
Antineoplastic Agent

Action and Clinical Pharmacology: Although Dacarbazine's exact mechanism of action is not known. 3 hypotheses have been offered:

1. Inhibition of DNA synthesis by acting as a purine analog.
2. Action as an alkylating agent.
3. Interaction with SH groups.

Dacarbazine is only slightly (approximately 5%) protein bound. Its plasma half-life after i.v. administration is approximately 35 minutes. In animals, approximately 46% of a radio labeled dose was recovered from the urine after 6 hours. Of this 46%, almost 50% was unchanged. Dacarbazine and a like quantity was AIC (amino imidazole carboxamide) a metabolite. Dacarbazine is subject to renal tubular secretion.

Indications and Clinical Uses: Palliative therapy of metastatic malignant melanoma.

Contra-Indications: Known hypersensitivity to Dacarbazine.

Precautions: Dacarbazine should be administered under the supervision of qualified physician experienced in the use of cancer chemotherapeutic agents. The drug should be administered to patients who are hospitalized and who can be observed carefully and frequently during and after therapy.

Dacarbazine is toxic to the hemopoietic system and may produce depression of the bone marrow, anemia, leukopenia, thrombocytopenia and bleeding. Leukopenia and thrombocytopenia may be severe enough to cause death. A careful monitoring of hematologic changes is required during and after therapy. Hemopoietic toxicity may warrant temporary suspension or cessation of Dacarbazine therapy. If Dacarbazine is used in combination with other cytotoxic agents, the toxic effects may be potentiated. Studies have demonstrated that Dacarbazine has a carcinogenic and teratogenic effect when used in animals. In the treatment of each patient, the possibility of achieving therapeutic benefit must be weighed carefully against the risk of toxicity. During i.v. Dacarbazine administration, exercise care to avoid s.c. or perivascular extravasation. Extravasation may result in tissue damage necrosis and severe pain.

Adverse Reactions: Hemopoietic depression: see precautions. Anorexia, nausea and vomiting are experienced in over 90% of patients with the initial doses. Restriction of food and fluid intake for 4 to 6 hours prior to treatment is recommended. Nausea and vomiting may last 1 to 12 hours and may be palliated by antiemetic therapy. After the first few days of treatment, the gastrointestinal symptoms tend to subside. Rarely, intractable nausea and vomiting may necessitate discontinuance of the drug. Diarrhea is uncommon but has been reported. There have been reports of significant impairment of liver and kidney function. Monitoring of liver and kidney function is recommended. Less than 10% of patients have experienced an influenza like syndrome of fever to 39 C, myalgia and malaise. These symptoms most frequently occur after large single doses some 7 days after treatment and last for 7 to 21 days. On successive treatment this syndrome may recure. In these cases, supportive management is recommended. Alopecia has been noted as has facial flushing and facial paresthesia.

Symptoms and treatment of overdose:

Symptoms: Accidental Dacarbazine overdosage would be expected to intensify hemopoietic depression and gastrointestinal symptomatology.

Treatment: Should be supportive, with particular attention to fluid balance in the acute phase. Monitor the hemopoietic system and institute appropriate therapy on the basis of these findings.

Dosage and administration: 2 to 4.5 mg/kg/day for 10 days which may be repeated at 3-week intervals. It has been found that Dacarbazine may be as efficacious at the lower dosage as at the higher dosage. Combinations of cancer chemotherapeutic agents have often shown an improved response over the use of single agents.

Administration: The 200 mg/vial is reconstituted with 19.7 mL of Sterile Water for Injection, USP. The resulting solution contains an equivalent of 10 mg/mL of Dacarbazine having a pH of 3.0 to 4.0. After the solution has been prepared the calculated dose of the resulting solution is drawn into a syringe and injected i.v. Injection of Dacarbazine may be completed in approximately 1 minute. Any solution remaining in the vial may be stored at 4 C for 72 hours. At 20 C the solution is not stable for more than 8 hours.

The reconstituted solution may be further diluted with 5% dextrose injection, USP, or sodium chloride injection, USP and administered as an i.v. infusion. The resulting solution may be stored at 4 C for up to 24 hours or at normal room conditions for up to 8 hours.

Availability and Storage: Each vial contains: Sterile Dacarbazine U.S.P 200 mg.

Ingredients: Citric Acid, Mannitol.

Dosage: As directed by the physician.

Instructions: Store at 2 to 8° C. Protect from heat, light and moisture. Keep all medicines out of the reach of children.To be sold on prescription of registered medical practitioner.

ڈاربازین 200ملی گرام انجکشن

(ڈاکاربازین) یو۔ایس۔پی

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: 2 سے 8 ڈگری سینٹی گریڈ پر رکھیں۔گرمی، نمی اور روشنی سے بچائیں۔تمام ادویات بچوں کی پہنچ سے دور رکھیں۔صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by:

PHARMEDIC LABORATORIES (PVT) LIMITED.

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