DAZINE (Dacarbazine)

Composition :

Dazine 100

Each vial contains

Dacarbazine USP ..... 100 mg

as a sterile, freeze-dried powder for reconstitution

Dazine 200

Each vial contains

Dacarbazine USP ..... 200 mg

as a sterile, freeze-dried powder for reconstitution

Dazine 500

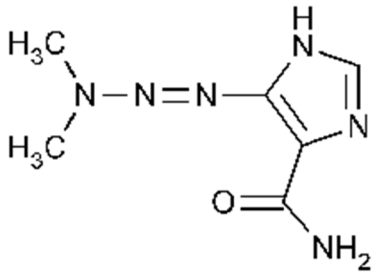
Each vial contains

Dacarbazine USP ..... 500 mg

as a sterile, freeze-dried powder for reconstitution

Description :

Dacarbazine is an anticancer agent. Although the exact mechanism of action of dacarbazine is not known, three hypotheses put forth are 1) inhibition of DNA synthesis by acting as a purine analog,2) action as an alkylating agent and 3) interaction with SH groups.



Indications :

Dazine is indicated in the treatment of metastatic malignant melanoma, Hodgkin' disease as a secondary-line therapy when used in combination with other effective agents, neurobiastoma, soft-tissue sarcoma including leiamyosarooma.

Dosage and Administration :

Malignant Melanoma. The recommended dosage of Dazine is 2 to 4.5mg/kg/day for 10 days. Treatment may be repeated at 4-week intervals. An alternate recommended dosage is 250mg/square meter body surface/day I.V. for 5 days. Treatment may be repeated every 3 weeks.

Hodgkin' Disease : The recommended dosage of Dazine in the treatment of Hodgkin' disease is 150mg/square meter body surface/day for 5 days, in combination with other effective drugs. Treatment may be repeated every 4 weeks. An alternative recommended dosage is 375mg/square meter body surface on day 1, in combination with other effective drugs, to be repeated every 15 days.

Other : Combination with other antineoplastic agents. Dosage of Dazine must be based on the clinical hematologic response and tolerance of the patient in order to obtain optimal therapeutic results.

Dacarbazine 100mg/vial, 200mg/vial and 500mg/vial are reconstituted with 9.9ml, 19.7ml and 50 ml respectively of Sterile Water for injection. The resulting solution contains 10mg/ml of dacarbazine having a pH of 3.0 to 4.0. The calculated dose of the resulting solution is drawn into a syringe and administered only intravenously.

The reconstituted solution may be further diluted with 5% dextrose injection, or sodium chloride injection and administered as an intravenous infusion.

After reconstitution and prior to use, the solution in the vial may be stored at 40C for up to 72 hours or at normal room conditions (temperature and light) for up to 8 hours. If the reconstituted solution is further diluted in 5% dextrose, injection or sodium chloride injection the resulting solution may be stored 40C for up to 24 hours or at normal room conditions for up to 8 hours.

Warnings:

Hemopletic, depression is the most common toxicity with dacarbazine and involves primarily the leukocytes and platelets, although, anemia may sometimes occur. Leukopenia and thrombocytopenia may be severe enough to cause death. The possible bone marrow depression requires careful monitoring of white blood cells, red blood cells, and platelet levels, Haemopiotic toxicity may warrant temporary suspension or cessation of therapy with dacarbazine.

Precautions :

Hepatic toxicity accompanied by hepatic vein thrombosis and hepatocellular necrosis resulting in death, has been observed mostly when dacarbazine has been administered concomitantly with other anti-neuplastic drugs, however, it has also been reported in some patients treated with DTIC-Dome alone.

Anaphylaxis can occur following the administration of dacarbazine.

Adverse Reactions

Hematologic : Pancytopenia, anemia, leukopenia, thrombocytopenia may occure, therefore careful monitoring is needed if any symptom occurs the administration should be discontinued or appropriate therapy instituted.

Hepatic : Increase of SGOT - total billirubin level, decrease of serum total protein may occur, Hepatic impairment accompanying be hepatic vein thrombosis and hepatocellular necrosis has been reported, if they occur, the administration should be discontinued or appropriated therapy instituted.

Renal: Increase of BUN, proteinuria may occur.

Hypersensitivity : Anaphylaxis photosensitivity may occur.

Gastrointestinal : Nausea, vomiting, anorexia, diarrhoea, gastralgia may occur.

Nervous system : Erythematous eruption, urticaria, alopecia may occur.

Dermatologic : Erythematours eruption, urticaria, alopecia may occur.

Site of Injection : Vascular pain may occur.

Other Malaise, myalgia, headache rubor, flush, influenza-like syndrome may occur.

DRUG INTERACTIONS

Concomitant therapy with other anti-neoplastic drugs or radio therapeutics may increase side-effect including bone marrow depression.

PREGNANCY

Pregnancy “Category C” - There are no adequate and well controlled studies in pregnant women. Dazine sould be used during pregnancy only if the potential risk to the fetus.

NURSING MOTHER

It is not known whether this drug is excreted in human milk, Because many drugs are excreted in human milk nad because of the potential for turmorigencity shown for dacarbazine in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

PEDIATRIC USE

Safely and effectiveness of Dazine in pediatric patients have not been established.

Overdosage

Give supportive treatment and monitor blood cell counts.

Contraindication:

Dazine is contraindicated in patients who have deermotrated a hypersensitivity to it in the past.

Storage

Preserve in seated containers. Store at 2-80C , protect from light. After reconstitution and prior to use, the solution in the vial may be stored at for 40C for up to 72 hours or at normal room conditions (temperature and light) for up to 8 hours. If the reconstituted solution is further diluted, the resulting solution may be stored at 40C for up to 24 hours.

Presentation:	Dazine 100	Vial of 20 ml
	Dazine 200	Vial of 20 ml
	Dazine 500	Vial of 50 ml

Manufactured in India by:

ZUVIUS LIFESCIENCES PVT. LTD.
A WHO-GMP CERTIFIED COMPANY
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