

Safety Alert

Jun 2024

Dacarbazine – Extension of the period of contraception for women of childbearing potential due to the genotoxic potential of dacarbazine

EDA performs label update to include the following:

Special warnings and precautions for use

Women of childbearing potential/contraception in men and women Due to the genotoxic potential of dacarbazine women of childbearing potential should use effective contraceptive measures while being treated with Dacarbazine medac and for 6 months following completion of treatment. Men are recommended to use effective contraceptive measures and to not father a child while receiving Dacarbazine medac and for 3 months following completion of therapy. Patients considering pregnancy should seek genetic counselling after the period of contraceptive use.

4.6 Fertility, pregnancy and lactation

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Background:

Therapeutic Indication

Dacarbazine is indicated for the treatment of patients with metastasised malignant melanoma.

Further indications for dacarbazine as part of a combination chemotherapy are:

- advanced Hodgkin's disease.
- advanced adult soft tissue sarcomas (except mesothelioma, Kaposi sarcoma).

References:

HPRA ([Click here](#))