February 2024

medac
Gesellschaft für klinische Spezialpräparate mbH
Theaterstr. 6
22880 Wedel
Germany

Important information for healthcare professionals:
Extension of the period of contraception for women of childbearing potential

Dacarbazine medac 200 mg, powder for solution for injection/infusion (PA 0623/003/002)
Dacarbazine medac 500 mg, powder for solution for infusion (PA 0623/003/003)
Dacarbazine medac 1000 mg, powder for solution for infusion (PA 0623/003/004)

Dear Healthcare Professional,

According to the European Medicines Agency's Safety Working Party recommendation EMA/CHMP/SWP/74077/2020 concerning the duration of contraception following the end of treatment with a genotoxic drug, medac GmbH would like to inform you that sections 4.4 and 4.6 of the Summary of Product Characteristics of dacarbazine-containing medac products have been updated regarding the specific period recommended for female patients of reproductive potential to use effective contraception during therapy and for at least 6 months after therapy. This recommendation has been added to the "Fertility, pregnancy and lactation" section of the Irish SmPC as follows:

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 treatment. In addition, patients are advised to seek advice on fertility preservation options before starting treatment with dacarbazine. After treatment with dacarbazine, patients planning pregnancy are advised to seek genetic counselling.

Section "Pregnancy, breast-feeding and fertility" of the Patient Information Leaflet has been updated respectively.

Additional updates include:

- Reduction of the period for contraception for men receiving dacarbazine from 6 months to 3 months following completion of therapy
- New information regarding fertility preservation and genetic counselling

Please ensure that all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

In addition to this communication, the updated product information for Dacarbazine medac is available on the HPRA website: Dacarbazine medac product information

The communication of this information is provided jointly from the Marketing Authorisation Holder (MAH) and local agent in the Republic of Ireland and has been agreed with the Health Products Regulatory Authority (HPRA).

MAH: medac, Theaterstr. 6, 22880 Wedel, Germany
Local agent: Fannin Ltd, South County Business Park, Leopardstown, Dublin 18

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance. Website: www.hpra.ie.

Adverse events should also be reported to the local agent Fannin Ltd via email to medical@dcccvital.com or Tel: +353 1 290 7000 or the MAH medac GmbH via email to drugsafety@medac.de.

If you have any questions, please also contact Fannin Ltd Medical Information by email on medical@dcccvital.com or medac GmbH by email on drugsafety@medac.de.

Yours sincerely,

Dr. med. Barbara Jogereit
EU Qualified Person for Pharmacovigilance

On behalf of medac GmbH