

Safety Alert

March 2022

A new warning about temozolomide concerning duration of contraception following the end of treatment with a genotoxic drug.

EDA performs label update to include the following:

Special warnings and precautions

Female patients

Women of childbearing potential have to use effective contraception to avoid pregnancy while they are receiving TMZ, and for at least 6 months following completion of treatment.

Male patients

Men being treated with TMZ should be advised not to father a child for at least 3 months' after receiving the last dose and to seek advice on cryoconservation of sperm prior to treatment

Background on the safety concerns

Therapeutic indications

Temozolomide hard capsules is indicated for the treatment of:

adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment.

children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.

Fertility, pregnancy and lactation

Women of childbearing potential

Women of childbearing potential have to use effective contraception to avoid Pregnancy should be advised to use effective contraception to avoid pregnancy while they are receiving TMZ, and for at least 6 months following completion of treatment.

Male fertility

TMZ can have genotoxic effects. Therefore, men being treated with it should use effective contraceptive measures and be advised not to father a child for at least 3 to 6 months after receiving the last dose and to seek advice on cryoconservation of sperm prior to treatment, because of the possibility of irreversible infertility due to therapy with TMZ.

References:

EMA ([Click here](#))