

SFDA

Safety communication

[12/03/2025]

Recommendation Regarding Use of Contraceptives Post-Anticancer Therapy with Genotoxic Medications.

The Saudi Food and Drug Authority (SFDA) would like to notify healthcare professionals about the importance of the calculation of contraception used post-therapy with genotoxic anticancer medicines to minimize the risk of embryotoxicity and teratogenicity. These recommendations pertain to both potential genotoxic metabolites and direct genotoxic effects.

The SFDA observed reports from global health authorities indicating that genotoxic anticancer medicines have been identified to potentially cause reproductive harm due to DNA damage in sperm and oocytes, leading to serious adverse reactions including, embryotoxicity and teratogenicity.

Therefore, it is crucial to use effective contraceptive methods during and after the completion of therapy to ensure the safety of any potential pregnancy.

The SFDA advises healthcare professionals to ensure:

- 1- Female Patients and Partners of Male Patients receiving genotoxic anticancer will use effective contraception for the duration of the genotoxic anticancer presence in the system (calculated as five half-lives from the last dose) and up to an additional six months.
- 2- Female patients and female sexual partners of male patients receiving pure aneugenic pharmaceuticals, will use effective contraception for the duration of the aneugenic product presence in the system (calculated as five half-lives from the last dose) and up to an additional one month.
- 3- For male patients, advise the use of effective contraception for the duration of the drug's presence in the system (calculated as five half-lives from the last dose) plus 90 days to cover a full sperm cycle.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

Website: <https://ade.sfda.gov.sa>

SFDA RMM Webpage:

