



On March 21, 2024, the Food and Drug Administration approved safety labeling changes for fluorouracil injection products.¹

From 5.1 Serious Adverse Reactions from Dihydropyrimidine Dehydrogenase (DPD) Deficiency:

"Patients who are homozygous or compound heterozygous for no function DPYD variants (i.e., carry two no function DPYD variants) or are compound heterozygous for a no function DPYD variant plus a decreased function DPYD variant have complete DPD deficiency and are at increased risk for acute early-onset of toxicity and serious life-threatening, or fatal adverse reactions due to increased systemic exposure to fluorouracil..."

Consider testing for genetic variants of DPYD prior to initiating fluorouracil to reduce the risk of serious adverse reactions if the patient's clinical status permits and based on clinical judgement...

From 12.5 Pharmacogenomics:

*Four DPYD variants have been associated with impaired DPD activity in White populations, especially when present as homozygous or compound heterozygous variants: c.1905+1G>A (DPYD *2A), c.1679T>G (DPYD *13), c.2846A>T, and c.1129-5923C>G (Haplotype B3)... The decreased function DPYD variant c.557A>G is observed in individuals of African ancestry.*

From 17 Patient Counseling Information:

*Advise: Inform patients of the potential for serious and life-threatening adverse reactions due to DPD deficiency and discuss with your patient whether they should be tested for genetic variants of DPYD that are associated with an increased risk of serious adverse reactions from the use of fluorouracil."*¹



RIGHTMED FOR ONCOLOGY

The new RightMed® Oncology panel test, DPYD single-gene test and original RightMed comprehensive test cover all five variants now referenced in the fluorouracil injection labeling.

Contact us today for help implementing a pharmacogenomic (PGx) program for your health system or oncology practice.



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1. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-safety-labeling-changes-regarding-dpd-deficiency-fluorouracil-injection-products>.

Example language taken from Gland Pharma Limited packaging insert.

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