FDA Safety Alerts

The U.S. Food and Drug Administration (FDA) recently issued safety alerts addressing newly identified concerns for medications across multiple classes. The following table summarizes the recommendations.

Drug	Issue	Recommendation
Obeticholic Acid (Ocaliva®) Obeticholic acid warning	Patients received daily medication, instead of approved weekly administration. Supratherapeutic dosing may lead to liver decompensation, liver failure, or death.	Calculate patient-specific Child-Pugh score to determine appropriate dosing regimen. Continue monitoring liver function throughout therapy.
Clarithromycin (Biaxin®) Clarithromycin warning	Drug may cause increased risk of heart problems or death. Problems may not be present until years after medication exposure. Exposure may be as short as two weeks.	Weigh risk v. benefit prior to initiation, particularly for patients with existing heart disease. Consider alternative antibiotic agent whenever possible. Advise patients with drug exposure to recognize signs and symptoms of heart disease.
Lamotrigine (Lamictal®) Lamotrigine warning	Drug may cause increased risk of hemophagocytic lymphohistocytosis (HLH), an uncontrolled inflammatory response by the immune system. HLH may lead to hospitalization and death if not diagnosed and treated quickly.	Be prepared to promptly recognize signs and symptoms of HLH. Discontinue drug if HLH or other serious immune-related adverse reaction is suspected with unknown etiology.
Pembrolizumab (Keytruda®) and Atezolizumab (Tecentriq®) Pembrolizumab and atezolizumab warning	Use of either drug as monotherapy may result in decreased survival when used to treat patients with metastatic urothelial cancer who have not received prior therapy **and** who have low expression of the protein programmed death ligand 1 (PD-L1).	Use of either drug is restricted to patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing therapy. Companion diagnostic test is required to determine PD-L1 levels in tumor tissue from patients with locally advanced or metastatic urothelial cancer who are cisplatin-ineligible
Dolutegravir-containing regimens (Tivicay®, Juluca®, Triumeq®)	Drugs may cause increased risk of neural tube birth defects when taken early in pregnancy.	Inform women of childbearing age about the potential risk of neural tube defects. Reinforce the importance of consistent use of effective birth control for women receiving these agents.

Dolutegravir-containing drug warning		
Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors SGLT2 warning	Drug may cause increased risk of necrotizing fasciitis or Fournier's gangrene.	Assess patients for Fournier's gangrene if redness, tenderness or swelling is present near genitals or rectum, with accompanying fever ≥100.4°. Treat suspected Fournier's gangrene immediately with broad-spectrum antibiotics and surgical debridement and discontinue use of SGLT2 inhibitor.
Fingolimod (Gilenya®) Fingolimod warning	Multiple Sclerosis (MS) symptoms may worsen upon discontinuation of drug. Worsening may result in permanent disability.	Before starting treatment, inform patients about the potential risk of severe increase in disability upon discontinuation of fingolimod. Carefully monitor patients upon discontinuation and treat any exacerbations appropriately.