

Brand Name	Generic Name	Indications	Route of Administration	Action
Comtan	entacapone	Parkinson's Disease	Oral	The FDA announced that there is no increased risk of prostate cancer with the use of entacapone [ie, Comtan[®] (entacapone) and Stalevo[®] (carbidopa/levodopa/entacapone)] to treat Parkinson's disease (PD) and the recommendations for using these medicines will remain the same as labeled in the prescribing information.
Ibrance	palbociclib	HR +, HER2-negative advanced or metastatic breast cancer	Oral	The FDA announced that the Warnings and Precautions sections of the Ibrance (palbociclib), Kisqali (ribociclib), and Verzenio (abemaciclib) drug labels were updated with information regarding interstitial lung disease (ILD) and pneumonitis . Severe, life-threatening, or fatal ILD and/or pneumonitis can occur in patients treated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitors, including Ibrance, Kisqali and Verzenio when taken in combination with endocrine therapy.
Kisqali	ribociclib	HR +, HER2-negative advanced or metastatic breast cancer	Oral	The FDA announced that the Warnings and Precautions sections of the Ibrance (palbociclib), Kisqali (ribociclib), and Verzenio (abemaciclib) drug labels were updated with information regarding interstitial lung disease (ILD) and pneumonitis . Severe, life-threatening, or fatal ILD and/or pneumonitis can occur in patients treated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitors, including Ibrance, Kisqali and Verzenio when taken in combination with endocrine therapy.

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Mavyret	glecaprevir/pibrentasvir	Chronic Hepatitis C	Oral	The FDA announced that the use of Mavyret™ (glecaprevir/pibrentasvir), Zepatier® (elbasvir/grazoprevir), or Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) to treat chronic hepatitis C (CHC) in patients with moderate to severe liver impairment has resulted in rare cases of worsening liver function or liver failure.
Stalevo	carbidopa/levodopa/entacapone	Parkinson's Disease	Oral	The FDA announced that there is no increased risk of prostate cancer with the use of entacapone [ie, Comtan® (entacapone) and Stalevo® (carbidopa/levodopa/entacapone)] to treat Parkinson's disease (PD) and the recommendations for using these medicines will remain the same as labeled in the prescribing information.
Venclexta	venetoclax	Treatment of adult patients with CLL or small lymphocytic lymphoma; in combination with azacitadine/decitabine/cytarabine for treatment of AML in adults 75 years and older who have comorbidities that preclude use of intensive induction chemotherapy	Oral	The FDA approved an update to the Warnings and Precautions section of the Venclexta (venetoclax) drug label, regarding increased mortality in patients with multiple myeloma when Venclexta is added to Velcade® (bortezomib) and dexamethasone. In a randomized trial in patients with relapsed or refractory multiple myeloma, the addition of Venclexta to bortezomib plus dexamethasone, a use for which Venclexta is not indicated, resulted in increased mortality.

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Verzenio	abemaciclib	HR +, HER2-negative advanced or metastatic breast cancer	Oral	The FDA announced that the Warnings and Precautions sections of the Ibrance (palbociclib), Kisqali (ribociclib), and Verzenio (abemaciclib) drug labels were updated with information regarding interstitial lung disease (ILD) and pneumonitis . Severe, life-threatening, or fatal ILD and/or pneumonitis can occur in patients treated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitors, including Ibrance, Kisqali and Verzenio when taken in combination with endocrine therapy.
Vosevi	sofosbuvir/velpatasvir/ voxilaprevir	Chronic Hepatitis C	Oral	The FDA announced that the use of Mavyret™ (glecaprevir/pibrentasvir), Zepatier® (elbasvir/grazoprevir), or Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) to treat chronic hepatitis C (CHC) in patients with moderate to severe liver impairment has resulted in rare cases of worsening liver function or liver failure .
Xeljanz/Xeljanz XR	tofacitinib	Rheumatoid Arthritis, psoriatic arthritis, ulcerative colitis.	Oral	The FDA announced that new warnings will be added to the tofacitinib (Xeljanz, Xeljanz XR) drug label regarding an increased risk of pulmonary embolism and death with the 10 mg twice daily dose in patients with ulcerative colitis (UC) .

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Zantac	ranitidine	OTC: Prevention and relief of heartburn associated with acid indigestion and sour stomach. RX: Treatment of duodenal ulcer, hypersecretory conditions, gastric ulcer, GERD, erosive esophagitis	Oral	The FDA announced that some ranitidine medicines contain the nitrosamine impurity, N-nitrosodimethylamine (NDMA), at low levels. This safety alert affects both Rx and OTC versions. The FDA is working with international regulators and industry partners to determine the source of this impurity in ranitidine. The agency is examining levels of NDMA in ranitidine and evaluating any possible risk to patients. The FDA will take appropriate measures based on the results of the ongoing investigation and will provide more information as it becomes available.
Zepatier	elbasvir/grazoprevir	Chronic Hepatitis C	Oral	The FDA announced that the use of Mavyret™ (glecaprevir/pibrentasvir), Zepatier® (elbasvir/grazoprevir), or Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) to treat chronic hepatitis C (CHC) in patients with moderate to severe liver impairment has resulted in rare cases of worsening liver function or liver failure.