Brand Name/Drug Class	Generic Name	Indications	Route of Administration	Action
Dupixent	dupilumab	Moderate-to-severe atopic dermatitis, Moderate-to-Severe asthma	SQ Injection	On October 19, 2018, new warnings were added to the Dupixent drug label regarding judicious use in **eosinophilic conditions, treatment of acute asthma symptoms or deteriorating disease, and reduction of corticosteroid dosage**.
Epipen	epinephrine	Emergency treatment of allergic reactions	IM or SQ Injection	On November 2, 2018, the FDA announced that the **labels** attached to some EpiPen (epinephrine) 0.3 mg and EpiPen Jr (epinephrine) 0.15 mg auto-injectors, and the authorized generic versions, **may block access to the auto-injector and prevent the ability to easily access the product.** In a letter to healthcare professionals from Pfizer, the manufacturer of the Mylan EpiPen, the label sticker on the auto-injector unit may have been improperly applied, causing resistance when removing it from the carrier tube. The carrier tube is the immediate package in which the auto-injector is contained. In some cases, the patient or caregiver may not be able to quickly remove the epinephrine auto-injector from the carrier tube.
Fluoroquinolone Antibiotics: Avelox, Baxdela, Cipro, Levaquin	moxifloxacin, delafloxacin, ciprofloxacin, levofloxacin, ofloxacin (generic only)	Various infections	Oral, IV infusion	On December 20, 2018, the FDA announced that fluoroquinolone antibiotics can **increase the occurrence of rare but serious events of ruptures or tears in the main artery of the body, called the aorta.** These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death. Fluoroquinolones should not be used in patients at increased risk for aortic aneurysm unless there are no other treatment options available. — People at increased risk include those with a history of blockages or aneurysms (abnormal bulges) of the aorta or other blood vessels, high blood pressure, certain genetic disorders that involve blood vessel changes, and the elderly.

Brand Name/Drug Class	Generic Name	Indications	Route of Administration	Action
Gilenya	fingolimod	Relapsing forms of multiple sclerosis	Oral	On November 20, 2018, the FDA announced that a warning about the **potential risk of severe increase in disability when Gilenya (fingolimod) therapy is stopped** will be added to the Gilenya drug label and patient Medication Guide. Health care professionals should inform patients before starting Gilenya treatment about the potential risk of severe increase in disability after stopping therapy. When Gilenya is stopped, patients should be carefully observed for evidence of an exacerbation of their MS and treated appropriately. Patients should be advised to seek immediate medical attention if they experience new or worsened symptoms of MS after Gilenya is stopped.
Idhifa	enasidenib	Relapsed/refractory acute myeloid leukemia with IDH2 mutation	Oral	On November 29, 2018, the FDA announced that signs and symptoms of a life-threatening side effect called **differentiation syndrome are not being recognized in patients receiving Idhifa (enasidenib)**.In the manufacturer's latest Idhifa quarterly safety report (May 1, 2018 to July 31, 2018), there were five cases of death associated with differentiation syndrome in patients treated with the drug. If patients experience unexplained respiratory distress or other symptoms, a diagnosis of differentiation syndrome should be considered and treatment with oral or intravenous corticosteroids should be given promptly. — Other symptoms of differentiation syndrome include acute respiratory distress represented by dyspnea and/or hypoxia and a need for supplemental oxygen; pulmonary infiltrates and pleural effusion; fever; lymphadenopathy; bone pain; peripheral edema with rapid weight gain; pericardial effusion; and hepatic, renal, and multiorgan dysfunction.

Brand Name/Drug Class	Generic Name	Indications	Route of Administration	Action
Lemtrada, Campath	alemtuzumab	Relapsing forms of multiple sclerosis	IV Infusion	On November 29, 2018, the FDA announced that a new warning about the rare but serious cases of **stroke and tears in the lining of arteries in the head and neck occurring in patients taking Lemtrada (alemtuzumab)** will be added to the Lemtrada drug label and patient Medication Guide. The risk of stroke will also be added to Lemtrada's Boxed Warning. The safety update is based on the identification of 13 cases of ischemic and hemorrhagic stroke or arterial dissection that occurred shortly after the patient received Lemtrada. These cases were reported in the FDA Adverse Event Reporting System database. — Most patients taking Lemtrada who developed stroke or tears in the artery linings, developed symptoms within 1 day of receiving Lemtrada. One patient reported symptoms that occurred 3 days after treatment. One case resulted in death. — Most of the cases did not provide sufficient detail to allow a full assessment of individual risk factors. However, the occurrence of these adverse events within one day of Lemtrada administration suggests an association. — The adverse events occurred within the same time frame as cytokine release syndrome, which is known to occur after Lemtrada administration and may contribute to these adverse events. However, in many cases, insufficient information was reported to determine whether cytokine release syndrome occurred together with stroke or arterial dissection. - Alemtuzumab is also approved under the brand name Campath®, which is indicated as a single agent for the treatment of B-cell chronic lymphocytic leukemia. The Campath drug label will also be updated to include these risks in the Adverse Reactions section under Postmarketing Experience.
Regranex	becaplermin	Lower extremity diabetic neuropathic ulcers	Topical	On November 28, 2018, the FDA approved the **removal of the Boxed Warning** and the warning in the Warnings and Precautions section of the Regranex (becaplemin) drug label **regarding increased rate of mortality secondary to malignancy.**

Brand Name/Drug Class	Generic Name	Indications	Route of Administration	Action
Seroquel/Seroquel XR	quetiapine	Schizophrenia, bipolar disorder; major depressive disorder--adjunctive treatment--Seroquel XR only	Oral	On November 29, 2018, the FDA approved an update to the Warnings and Precautions section of the Seroquel (quetiapine) and Seroquel XR (quetiapine) drug labels regarding the **risk of anticholinergic (antimuscarinic) effects.** Norquetiapine, an active metabolite of quetiapine, has moderate to strong affinity for several muscarinic receptor subtypes. This contributes to anticholinergic adverse reactions when quetiapine-containing products are used at therapeutic doses, taken concomitantly with other anticholinergic medications, or taken in overdose. — Quetiapine should be used with caution in patients receiving medications having anticholinergic (antimuscarinic) effects. — Constipation was a commonly reported adverse event in patients treated with quetiapine and represents a risk factor for intestinal obstruction. Intestinal obstruction has been reported with quetiapine, including fatal reports in patients who were receiving multiple concomitant medications that decrease intestinal motility. — Quetiapine should be used with caution in patients with a current diagnosis or prior history of urinary retention, clinically significant prostatic hypertrophy, or constipation, or increased intraocular pressure.

Brand Name/Drug Class	Generic Name	Indications	Route of Administration	Action
Taxotere	docetaxel	Breast Cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, head and neck cancer	IV Infusion	On October 5, 2018, the FDA approved an update to the Warnings and Precautions section of the Taxotere (docetaxel) drug label regarding the **risk of enterocolitis and neutropenic colitis**. Enterocolitis and neutropenic colitis (typhlitis) have occurred in patients treated with Taxotere alone and in combination with other chemotherapeutic agents, despite the coadministration of granulocyte-colony stimulating factor. — Caution is recommended for patients with neutropenia, particularly at risk for developing gastrointestinal complications. Enterocolitis and neutropenic enterocolitis may develop at any time, and could lead to death as early as the first day of symptom onset. — Patients should be closely monitored from onset of any symptoms of gastrointestinal toxicity. — Patients should be informed to contact their healthcare provider with new or worsening symptoms of gastrointestinal toxicity.