Approvals & Updates

October 2020

PharMerica®

New Drug Approvals

Gavreto (pralsetinib)

Indication: Non-small cell lung cancer (NSCLC)

Mechanism of Action: Kinase inhibitor

Dosage Form(s): Oral capsules

Comments: Gavreto is FDA-approved for treating adults with metastatic rearranged during transfection (*RET*) fusion-positive NSCLC as detected by an FDA approved test. Patients eligible to receive Gavreto should be based on the presence of a *RET* gene fusion. Gavreto is given by mouth at a dose of 400mg once daily on an empty stomach, with no food for a minimum of 2 hours before and 1 hour after drug administration. Therapy should be continued until disease progression or unacceptable toxicity. Gavreto carries labeled warnings for interstitial lung disease/pneumonitis, hypertension, hepatotoxicity, hemorrhagic events, risk of impaired wound healing, and embryo-fetal toxicity. Blood pressure should be monitored at baseline, 1 week after therapy, at least monthly thereafter, and as clinically necessary. Liver function tests (ALT/AST) should be monitored at baseline, every 2 weeks for the first 3 months of therapy, monthly thereafter, and as clinically necessary. Additionally, pregnancy status should be confirmed prior to initiation, and signs and symptoms of interstitial lung disease, pneumonitis, hemorrhage, and impaired wound healing should be monitored. Depending on the severity of laboratory values and adverse events, Gavreto doses may need to be withheld, reduced, or discontinued. Concomitant administration of Gavreto with strong CYP3A inhibitors, combined P-glycoprotein and strong CYP3A inhibitors, and strong CYP3A inducers should be avoided; however, if concomitant administration is necessary, Gavreto doses will need to be adjusted. The most common adverse reactions (≥25%) and Grade 3-4 laboratory abnormalities (≥2 %) reported with Gavreto include fatigue, constipation, musculoskeletal pain, and hypertension and decreased lymphocytes, decreased neutrophils, decreased phosphate, decreased hemoglobin, decreased sodium, decreased corrected calcium, and increased ALT.

Safety Alerts

FDA requiring Boxed Warning updated to improve safe use of benzodiazepine drug class

Benzodiazepines are a common medication class used to treat conditions such as anxiety, insomnia, and seizure. In order to address the serious risks of abuse, addiction, physical dependence, and withdrawal reactions associated with benzodiazepines, especially when combined with other medications that depress the central nervous system, the FDA is requiring that all of them receive an update to their *Boxed Warning* that describes these serious risks. Additionally, other sections of the prescribing information (*Warnings and Precautions*, *Drug Abuse and Dependence*, and *Patient Counseling Information*) and patient medication guides will need to be updated describing benzodiazepine's various risks.

FDA warns about serious problems with high doses of the allergy medicine diphenhydramine (Benadryl)

Due to a recent trend amongst teenagers called the "Benadryl Challenge," which consists of consuming higher than recommended doses of diphenhydramine (Benadryl), the FDA published a safety warning describing the serious adverse effects associated with excessive consumption of this common over-the-counter allergy medication. Adverse effects include serious heart problems, seizures, coma, or even death. The public is advised to store diphenhydramine out of children's reach or sight and to always read and follow the Drug Facts label. Side effects associated with diphenhydramine or any medication are encouraged to be reported to the FDA's MedWatch program.

Current Drug Shortages

The following shortage has been recently identified by the FDA:

- Hydrocortisone tablets

For additional information on drug shortages, please contact the Center for Drug Information & Evidence-Based Practice.

Recently Approved Drug Combinations, Dosage Forms, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Alkindi Sprinkle (Hydrocortisone)	Adrenocortical insufficiency	Glucocorticoid	Oral granules	New dosage form
Onureg (Azacitidine)	Acute myeloid leukemia	Nucleoside metabolic inhibitor	Oral tablets	New dosage form
Qdolo (Tramadol)	Pain	Opioid agonist	Oral solution	New dosage form

Creighton University Center for Drug Information & Evidence-Based Practice

Drug Information Consultation Service

Monday through Friday

7:30am-3:30pm Central

1-800-561-3728

Voicemail service is available after-hours

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