College of Pharmacy and Pharmaceutical Sciences
WASHINGTON STATE UNIVERSITY

Drug Information Center

Highlights of FDA Activities – 5/1/2020 – 5/31/2020

FDA Drug Safety Communications & Drug Information Updates:

Remdesivir Emergency Use Authorization for COVID-19 Treatment 5/1/20

The FDA issued an emergency use authorization for remdesivir (Gilead Sciences) for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease. While data remains limited, results of a randomized placebo-controlled trial demonstrated a reduced time to recovery in some patients. The EUA allows remdesivir to be distributed in the U.S. and be administered intravenously by health care providers in the treatment of patients with severe disease, defined as patients with low blood oxygen levels or needing oxygen therapy or mechanical ventilation. Fact sheets for health care providers and patients are available on the FDA site.

Fraudulent COVID-19 Medical Products & Project Quack Hack 5/7/20

The FDA provided an update on actions taken to combat fraudulent COVID-19 medical products, including issuance of 42 warning letter to companies making bogus health claims and hundreds of abuse complaints to domain name registrars and internet marketplaces, as well as identification of hundreds of products including fraudulent drugs, testing kits and personal protective equipment sold online with unproven claims. The agency encourages anyone aware of suspected fraudulent medical products for COVID-19 to report them to the FDA at FDA-COVID-19-Fraudulent-Products@fda.hhs.gov

Nitrosamine Impurity in Metformin Extended-Release Products – Drug Information Update 5/28/20

The FDA announced laboratory testing had detected levels of N-nitrosodimethylamine (NDMA) above the agency's acceptable level in several lots of extended-release metformin. The FDA has been in contact with five manufacturers to recommend voluntary recall of their products. Recalls will be posted on the FDA website. The first recall was announced in May (see below). NDMA has not been detected in immediate release formulations.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:

Lactated Ringers Injection, USP, ICU Medical: Recall – Particulate Matter 5/8/20

ICU Medical recalled one lot (07-514-FW) of lactated ringer's injection USP 1000 mL flexible container due to the presence of iron oxide particulate matter.

Finasteride Plus capsules 1.25 mg, MasterPharm, LLC.: Recall – Contains Undeclared Minoxidil 5/11/20

MasterPharm LLC. recalled one lot of compounded Finasteride Plus capsules 1.25 mg at the consumer level due to presence of undeclared minoxidil. The affected lot includes 02-27-2020:04@11 with a beyond use date of 8/25/20.

Cannabidiol (CBD) Complex, Curcumin Complex, and Cannabidiol + Curcumin Injectables, Biota Biosciences, LLC.: Recall – Marketed Without FDA Approval 5/20/20

Biota Biosciences, LLC. recalled to the consumer level two lots of injectable Cannabidiol CBD Complex 10 mL vials, two lots of injectable Curcumin Complex 10 mL vials, and one lot of injectable Cannabidiol + Curcumin 10 mL vials because they were marketed without FDA approval and additionally were not labeled with adequate directions for use. The complete list of recalled item codes and lot numbers can be found on an announcement on the FDA site.

NP Thyroid tablets 30 mg, 60 mg, and 90 mg, Acella Pharmaceuticals, LLC.: Recall – Super Potency 5/22/20

Acella Pharmaceuticals, LLC. recalled 13 lots of NP Thyroid tablets 30 mg, 60 mg, and 90 mg due to a higher level of liothyronine (T3) than indicated on the labeling. A complete list of recalled item codes and lot numbers can be found on an announcement on the FDA site.

Metformin Extended-Release Tablets 500 mg, Apotex Corp: Recall – Contains Unacceptable Amounts of NDMA 5/28/20

Apotex Corp recalled to the retail level all lots within expiry of metformin extended-release tablets 500 mg due to levels of NDMA in excess of the acceptable daily intake limit. All lots with the NDC 60505-0260-1 are affected.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding undeclared active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

Product	***Undeclared Ingredient(s) or Contaminants***
KORE ORGANIC Watermelon CBD Oil Tincture, 30 mL bottle*	Lead

*recalled

New Product Shortages	***Date Initially Posted***
Amifostine injection	5/21/20
Azithromycin tablets	5/20/20
Dimercaprol (Bal in oil) in injection USP	5/11/20
Famotidine injection	5/5/20
Famotidine tablets	5/4/20
Hydrocortisone tablets, USP	5/15/20
Leucovorin calcium lyophilized powder for injection	5/15/20
Sertraline HCl oral solution	5/26/20
Sertraline HCl tablets	5/29/20
Timolol maleate ophthalmic gel forming solution	5/29/20
Timolol maleate ophthalmic solution	5/29/20
Vecuronium bromide for injection	5/6/20

Discontinuations/Withdrawals of Proprietary or Sole-Source Products	***Date Posted***
Betrixaban capsules (Bevyxxa, Portola Pharmaceuticals, Inc); use alternative agent for venous thromboembolism prophylaxis	5/1/20
Aspirin/Dipyridamole ER (Aggrenox; BIPI); generic equivalents remain available	5/26/20
Nevirapine tablets (Viramune; BIPI); generic equivalents remain available	5/29/20

New Drug Approvals:	***Description***	***Date Approved***
Capmatinib / Tabrecta / Novartis Pharmaceuticals Corp.	Kinase inhibitor for the treatment of metastatic non-small cell lung cancer in patients whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping (See Attached Drug Summary)	5/6/20
Selpercatinib / Retevmo / Loxo Oncology	Kinase inhibitor for the treatment of RET fusion-positive non-small cell lung cancer, RET-mutant medullary thyroid cancer, or RET fusion positive thyroid cancer requiring systemic therapy (See Attached Drug Summary)	5/8/20
Ripretinib / Qinlock / Deciphera Pharmaceuticals, LLC	Kinase inhibitor for the treatment of advanced gastrointestinal stromal tumor (GIST) in patients who have received prior treatment with 3 or more kinase inhibitors (See Attached Drug Summary)	5/15/20

New Drug Approvals: continued

Fluoroestradiol F 18 injection / Cerianna / Zionexa USA	A radioactive diagnostic indicated for use with positron emission tomography (PET) imaging for the detection of estrogen receptor (ER)-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer	5/20/20
Artesunate for injection / Amivas LLC	IV artemisinin derivative for initial treatment of severe malaria (See Attached Drug Summary)	5/26/20
Flortaucipir F 18 injection / Tauvid / Avid Radiopharmaceuticals	A radioactive diagnostic indicated for positron emission tomography (PET) imaging of the brain to estimate the density and distribution of aggregated tau neurofibrillary tangles (NFTs) in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease	5/28/20

New Indications:	***Description***	***Date Approved***
Dapagliflozin / Farxiga / AstraZeneca Pharmaceuticals	To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II to IV) with reduced ejection fraction; recommended dose is 10 mg once daily	5/5/20
Olaparib / Lynparza / AstraZeneca Pharmaceuticals	In combination with bevacizumab for maintenance treatment of advanced ovarian cancer in patients who are in complete or partial response to first-line platinum-based chemotherapy or whose cancer is associated with homologous recombination deficiency (HRD) positive status	5/8/20
Pomalidomide / Pomalyst / Celgene	Treatment of Kaposi's sarcoma in patients who are HIV-negative	5/14/20
Pomalidomide / Pomalyst / Celgene	Treatment of AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy	5/14/20
Rucaparib / Rubraca / Clovis Oncology Inc	Treatment of patients with a deleterious BRCA mutation-associated metastatic castration-resistant prostate cancer who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy	5/15/20
Ipilimumab / Yervoy / Bristol-Myers Squibb	In combination with nivolumab for first-line treatment for patients with metastatic non-small cell lung cancer whose tumors express PD-L1, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations	5/15/20
Nivolumab / Opdivo / Bristol-Myers Squibb	In combination with ipilimumab for first-line treatment for patients with metastatic non-small cell lung cancer whose tumors express PD-L1, with no EGFR or ALK genomic tumor aberrations	5/15/20
Atezolizumab / Tecentriq / Genentech	First-line treatment of adults with metastatic non-small cell lung cancer whose tumors have high PD-L1 expression, with no EGFR or ALK genomic tumor aberrations	5/18/20
Olaparib / Lynparza / AstraZeneca Pharmaceuticals	Treatment of patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer who have progressed following treatment with enzalutamide or abiraterone	5/19/20
Brigatinib / Alunbrig / Takeda Pharmaceutical Company	Treatment of anaplastic lymphoma kinase positive (ALK+) metastatic non-small cell lung cancer as a first-line therapy	5/22/20

New Indications: continued

Dupilumab / Dupixent / Regeneron Pharmaceuticals, Inc.	Treatment of moderate-severe atopic dermatitis in children aged 6-11 years whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	5/26/20
Bedaquiline / Sirturo / Janssen Therapeutics	Indication expanded to include use as part of a combination regimen for the treatment pulmonary multi-drug resistant tuberculosis in pediatric patients 5 years and older and weighing at least 15 kg	5/27/20
Ticagrelor / Brilinta / AstraZeneca Pharmaceuticals	To reduce the risk of first myocardial infarction or stroke in patients with coronary artery disease at high risk for such events	5/28/20
Atezolizumab / Tecentriq / Genentech	In combination with bevacizumab for the treatment of patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy	5/29/20
Bevacizumab / Avastin / Genentech	In combination with atezolizumab for the treatment of patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy	5/29/20
Ramucirumab / Cyramza / Eli Lilly	In combination with erlotinib for the first-line treatment of patients with metastatic non-small cell lung cancer who have EGFR exon 19 deletions or exon 21 L858R mutations	5/29/20
Ixekizumab / Taltz / Eli Lilly	Treatment of active non-radiographic axial spondyloarthritis in patients with objectives signs of inflammation	5/29/20

New Dosage Form/Formulation:	***Description***	***Date Approved***
Daratumumab; hyaluronidase-fihj / Darzalex Faspro / Janssen Biotech	Injection: 120 mg; 2000 units/mL. Subcutaneous formulation approved for use in the treatment of multiple myeloma	5/1/20
Leuprolide acetate / Fensolvi / Tolmar	Kit, 45 mg leuprolide acetate for injectable suspension; subcutaneous use every 6 months for treatment of pediatric patients 6 years and older with central precocious puberty	5/1/20
Celecoxib / Elyxyb / Dr. Reddy's Laboratories Limited	Oral solution: 120 mg/4.8 mL supplied in a disposable glass bottle. For the acute treatment of migraine at a dose of 120 mg orally with or without food; patients should be instructed to drink the entire amount of solution from the bottle for the 120 mg dose, or to use an oral dosing syringe to measure a reduced dose as prescribed.	5/5/20
Apomorphine HCl sublingual film / Kynmobi / Sunovion Pharmaceuticals	Sublingual film: 10 mg, 20 mg, 25 mg, 30 mg; for the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease	5/21/20
L-lactic acid, citric acid, potassium bitartrate / Phexxi / Evofem Biosciences	Vaginal applicator: 5 g gel; Non-hormonal prescription gel for prevention of pregnancy administered up to one hour before vaginal intercourse	5/22/20
Solifenacin oral suspension / Vesicare LS / Astellas Pharma Inc.	Oral suspension: 5 mg/5 mL; for the treatment of neurogenic detrusor overactivity in pediatric patients aged 2 years and older	5/26/20
Minocycline topical foam / Zilxi / Foamix Pharmaceuticals Inc.	Foam 1.5%; for the treatment of inflammatory rosacea lesions in adults	5/28/20
Elagolix, estradiol, and norethindrone acetate / Oriahnn / Abbvie Inc.	Capsules: elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg (morning dose); estradiol 300 mg (evening dose); management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	5/29/20

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Capmatinib / *Tabrecta* / Novartis Pharmaceuticals Corp	
Generic Name / Brand Name / Company	Capmatinib / *Tabrecta* / Novartis Pharmaceuticals Corp
Date of approval	5/6/20
Drug Class (Mechanism of Action if novel agent)	Antineoplastic agent, tyrosine kinase inhibitor
Indication	Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.
Comparative agent – Therapeutic interchange?	Tyrosine kinase inhibitors – afatinib, gefitinib also approved treatment of NSCLC, although not for this specific mutation
Dosage forms/strengths	Tablet: 150 mg and 200 mg
Common Dose/sig	Take 400 mg orally twice daily with or without food. Dose modifications required for severe adverse reactions.
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Cabozantinib, *Capmist*, imatinib, *Tabradol*
Clinical Use Evaluation	
Common Adverse Effects	≥20%: peripheral edema, nausea, fatigue, vomiting, dyspnea, and decreased appetite.
Severe Adverse Effects	Peripheral edema, dyspnea, interstitial lung disease (ILD)/pneumonitis, hepatotoxicity, photosensitivity, embryo-fetal toxicity
Severe Drug-Drug Interactions	Strong and moderate CYP3A4 inducers: avoid concomitant use. CYP1A2, P-glycoprotein, BCRP, MATE1, and MATE2K substrates: if concomitant use unavoidable, reduce substrate dose
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver function, pregnancy, and presence of a mutation that leads to MET exon 14 skipping in tumor specimens as determined by an FDA-approved test.
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustment is recommended in patients with mild (baseline CrCl 60 to 89 mL/min) to moderate renal impairment (CrCl 30-59 mL/min). Capmatinib has not been studied in patients with severe renal impairment (CrCl 15 to 29 mL/min). No dosage adjustment necessary in mild, moderate, or severe hepatic impairment.

Capmatinib continued…	
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: While no contraindications are listed in the prescribing information, this medication should be avoided in patients with known or suspected hypersensitivity to capmatinib or any component of its formulation. Warnings: Interstitial lung disease/pneumonitis, hepatotoxicity, photosensitivity risk, embryotoxicity. Monitor for pulmonary symptoms: immediately withhold for suspected interstitial lung disease/pneumonitis.
Special administration technique or considerations	Tablets should be swallowed whole. Do not break, crush, or chew tablets. Do not make up missed or vomited doses, the next dose should be taken at its scheduled time. Any unused or remaining capmatinib should be discarded 6 weeks after first opening of the bottle.
Prepared by	Li Wei Chen
Source	Tabrecta (capmatinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2020.

Ripretinib / *Qinlock* / Deciphera Pharmaceuticals, LLC	
Generic Name / Brand Name / Company	Ripretinib / *Qinlock* / Deciphera Pharmaceuticals, LLC
Date of approval	5/15/20
Drug Class (Mechanism of Action if novel agent)	Tyrosine kinase inhibitor
Indication	Treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib
Comparative agent – Therapeutic interchange?	Tyrosine kinase inhibitors – imatinib, sunitinib, regorafenib
Dosage forms/strengths	Tablet: 50 mg
Common Dose/sig	Take 150 mg orally once daily with or without food. Dose reductions are recommended for adverse reactions.
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Regorafenib, imatinib, sunitinib, *Quinidex*, rilzabrutinib
Clinical Use Evaluation	
Common Adverse Effects	≥20%: alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, palmar-plantar erythrodysesthesia, vomiting, increase lipase, decreased phosphate.
Severe Adverse Effects	Palmar-plantar erythrodysesthesia, new primary cutaneous malignancies, hypertension, cardiac dysfunction, impaired wound healing, embryo-fetal toxicity
Severe Drug-Drug Interactions	Strong CYP3A4 inducers: avoid concomitant use Strong CYP3A inhibitors: monitor more frequently for adverse reactions
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Verify pregnancy status in females of reproductive potential prior to initiation of therapy
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dose adjustment is recommended in patients with mild hepatic impairment (total bilirubin ≤ULN and AST >ULN or total bilirubin 1 to 1.5 × ULN and AST any) or mild to moderate renal impairment. A recommended dosage has not been established for patients with moderate or severe hepatic impairment or severe renal impairment.

Ripretinib continued…	
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	**Contraindications:** While no contraindications are listed in the prescribing information, this medication should be avoided in patients with known or suspected hypersensitivity to ripretinib or any component of its formulation. **Warnings:** Palmar-plantar erythrodysesthesia, new primary cutaneous malignancies, hypertension, cardiac dysfunction, impaired wound healing, embryo-fetal toxicity. Monitor blood pressure and ejection fraction, and skin for new/evolving skin lesions.
Special administration technique or considerations	Tablets should be swallowed whole. Do not break, crush, or chew tablets. Administer at the same time each day. Do not make up vomited doses, the next dose should be taken at its scheduled time. If a dose is missed, take as soon as remembered if it is within 8 hours of scheduled dose. If more than 8 hours have passed, wait until next scheduled dose. Store in original container with desiccant to protect from moisture and light.
Prepared by	Kyle Bradley
Source	Qinlock (ripretinib) [prescribing information]. Waltham, MA: Deciphera Pharmaceuticals, LLC; May 2020.

Selpercatinib / *Retevmo* / Eli Lilly and Company	
Generic Name / Brand Name / Company	Selpercatinib / *Retevmo* / Eli Lilly and Company
Date of approval	5/8/20
Drug Class (Mechanism of Action if novel agent)	Antineoplastic agent, kinase inhibitor
Indication	Treatment of adults with metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC) Treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC) who require systemic therapy Treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic *RET* fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Capsule: 40 mg and 80 mg
Common Dose/sig	For patients weighing less than 50 kg: 120 mg twice daily by mouth until disease progression or unacceptable toxicity For patients weighing 50 kg or more: 160 mg twice daily by mouth until disease progression or unacceptable toxicity Dose modifications are recommended for severe adverse reactions.
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Secukinumab, selumetinib, *ReFacto, Retevase, Revatio*
Clinical Use Evaluation	
Common Adverse Effects	≥20%: elevated hepatic enzymes, hypoalbuminemia, dry mouth, diarrhea, fatigue, edema, constipation, nausea, headache, abdominal pain, hyperbilirubinemia
Severe Adverse Effects	Hepatotoxicity, hypertension, QT interval prolongation, hemorrhagic events, hypersensitivity, impaired wound healing

Selpercatinib continued…	
Severe Drug-Drug Interactions	Acid reducing agents: avoid concomitant use Strong and moderate CYP3A inhibitors: avoid concomitant use; if unavoidable, reduce selpercatinib dose Strong and moderate CYP3A inducers: avoid concomitant use CYP2C8 and CYP3A substrates: avoid concomitant use; if unavoidable, modify substrate drug dosage Drugs that prolong QT interval: monitor QT interval more frequently in patients who require treatment with concomitant medications known to prolong QT interval
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver function, electrolytes, TSH, pregnancy
Used in Pediatric Areas	Evaluated in patients 12 years of age and older with advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC) who require systemic therapy and patients 12 years of age and older with advanced or metastatic *RET* fusion-positive thyroid cancer who require systemic therapy and are radioactive iodine-refractory (if radioactive iodine is appropriate); safety and efficacy not evaluated in younger patients
Renal or Hepatic Dosing	Renal impairment: no dosage modification is recommended for patients with mild-moderate renal impairment (CrCl $\geq$ 30 mL/min); the recommended dose has not been established for patients with severe renal impairment (CrCl > 30 mL/min) Hepatic impairment: reduce the dose when administering selpercatinib to patients with severe hepatic impairment (total bilirubin greater than 3-10 times the upper limit of normal and any AST); no dosage modification is recommended for patients with mild or moderate hepatic impairment. Monitor closely for adverse reactions in hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: while no contraindications are listed in the prescribing information, this medication should be avoided in patients with known or suspected hypersensitivity to capmatinib or any component of its formulation. Warnings: hepatotoxicity, hypertension, QT interval prolongation, hemorrhagic events, hypersensitivity, risk of impaired wound healing, embryo-fetal toxicity
Special administration technique or considerations	May be taken with or without food unless concomitant use of an acid reducing agent is required. If concomitant use cannot be avoided: take selpercatinib with food when coadministered with a PPI; take selpercatinib 2 hours before or 10 hours after an H2 receptor antagonist; take selpercatinib 2 hours before or 2 hours after a locally-acting antacid Swallow capsules whole; do not crush or chew the capsules. Do not take a missed dose unless it is more than 6 hours until the time for the next scheduled dose. If vomiting occurs after administration, do not take an additional dose. Continue to the next scheduled time for the next dose. Due to risk of impaired wound healing: withhold selpercatinib for at least 7 days prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing.
Prepared by	Regan Smith
Source	Retevmo (selpercatinib) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; May 2020

Artesunate for Injection / Amivas LLC	
Generic Name / Brand Name / Company	Artesunate for injection / Amivas LLC
Date of approval	5/20/20
Drug Class (Mechanism of Action if novel agent)	Antimalarials, artemisinin derivatives
Indication	Initial treatment of severe malaria in adult and pediatric patients. Treatment of severe malaria with artesunate for injection should always be followed by a complete treatment course of an appropriate antimalarial regimen. Concomitant therapy with an antimalarial agent such as an 8-aminoquinoline drug is necessary for the treatment of severe malaria due to *Plasmodium vivax* or *Plasmodium ovale.*
Comparative agent – Therapeutic interchange?	Oral antimalarials – artemether/lumefantrine, atovaquone/proguanil
Dosage forms/strengths	Single-dose vials of powder for reconstitution with supplied sterile diluent: 110 mg
Common Dose/sig	2.4 mg/kg administered intravenously at 0 hours, 12 hours, and 24 hours, and thereafter, administered once daily until the patient can tolerate oral antimalarial therapy.
DEA Schedule	None
Date of market availability	2nd half of 2020; remains available under CDC-sponsored expanded access until commercially available
Similar Medication Names	Alendronate, artemether
Clinical Use Evaluation	
Common Adverse Effects	≥10%: anemia, elevated transaminases, thrombocytopenia, hyperbilirubinemia, acute renal failure, leukocytosis, hemoglobinuria, jaundice
Severe Adverse Effects	Post-treatment hemolysis, hypersensitivity reaction
Severe Drug-Drug Interactions	Ritonavir, nevirapine, or strong UDP-Glucoronosyltransferase (UGT) Inducers: monitor for reduced antimalarial efficacy of artesunate for injection Strong UGT Inhibitors: monitor for adverse reactions when co-administering artesunate with strong UGT inhibitors (e.g. axitinib, vandetanib, imatinib, diclofenac).
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor for evidence of hemolytic anemia for 4 weeks after treatment with artesunate for injection. A subset of patients with delayed hemolysis after artesunate therapy have evidence of immune-mediated hemolysis, so consider a direct antiglobulin test to determine if therapy (e.g. corticosteroids) is necessary.
Used in Pediatric Areas	Evaluated in pediatric patients 6 months and older. No dosage adjustment is necessary for pediatric patients.
Renal or Hepatic Dosing	**Renal Impairment:** No specific studies have been carried out in patients with renal impairment although most patients with severe malaria do present with a degree of renal impairment. No specific dosage adjustments are needed for patients with renal impairment. **Hepatic Impairment:** No specific studies have been carried out in patients with hepatic impairment although most patients with severe malaria do present with some degree of hepatic impairment. No specific dosage adjustments are needed for patients with hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	**Contraindications:** Serious hypersensitivity to artesunate **Warnings:** post-treatment hemolysis, hypersensitivity, embryo-fetal toxicity

Artesunate for Injection continued…	
Special administration technique or considerations	Artesunate for injection should be administered intravenously as a slow bolus over 1-2 minutes. Do **NOT** administer artesunate for injection as a continuous intravenous infusion. Administer artesunate for injection with an antimalarial agent that is active against the hypnozoite liver stage forms of *Plasmodium*, such as an 8-aminoquinolone drug, to patients with severe malaria due to *P. vivax* or *P. ovale*. Administer the constituted solution within 1.5 hours of constitution with the supplied diluent.
Prepared by	Kyle Bradley, Regan Smith
Source	Artesunate for injection [prescribing information]. Wilmington, DE: Amivas LLC; May 2020