WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 11/1/23 – 11/30/23

FDA Drug Safety Communications & Drug Information Updates:

Moderna COVID-19 Vaccine (2023-2024 Formula) – Pediatric Dosing 11/1/23
The FDA advised healthcare providers that administer the Moderna COVID-19 Vaccine (2023-2024 Formula) to patients 6 months through 11 years of age to ensure the correct volume of vaccine (0.25 mL) is withdrawn from the vial and administered. The single dose vial contains a larger volume than is necessary for a single dose, therefore attention should be paid to withdrawing the recommended dosage rather than the entire contents of the vial.

Cardinal Health Monoject Syringes – Do Not Use with Syringe Pumps and PCA Pumps 11/20/23
The FDA alerted health care providers and facilities not to use Cardinal Health Monoject syringes with syringe pumps and patient-controlled analgesia pumps while the FDA investigates the issue. These syringes differ from previously branded Covidien Monoject syringes as they have different dimensions and are made by a different contract manufacturer. The change in dimensions may result in recognition, compatibility, and pump performance issues. Both Cardinal Health and Covidien Monoject syringes state only "monoject" on the syringe itself. Covidien syringes should be stored with the outer packaging and may continue to be used with syringe pumps and PCA pumps.

DRESS with Levetiracetam and Clobazam – Drug Safety Communication 11/28/23
The FDA warned that Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) may occur with the antiseizure medications levetiracetam and clobazam. Although rare, these are severe reactions that may start as a rash and quickly progress resulting in injury to internal organs and death. Warnings about the risk are to be added to the prescribing information and Medication Guides for these medications.

BCMA-Directed or CD19-Directed Autologous CAR-T Therapy – Risk of T-cell Malignance 11/28/23
The FDA is investigating reports of T-cell malignancies, including chimeric antigen receptor (CAR)-positive lymphoma in patients who received treatment with BCMA- or CD19-directed autologous CAR T cell immunotherapies. Although the overall benefits of these products continue to outweigh their risks, the FDA is evaluating these reports and the need for regulatory action. Patients receiving treatment with these products should be monitored life-long for new malignancies.

Plastic Syringes Made in China – Potential Device Failures 11/30/23
The FDA is evaluating the potential for device failures with plastic syringes manufactured in China. At this time, the issue does not include glass syringes, pre-filled syringes, or syringes used for oral or topical purposes. While the FDA continues its evaluation, they advise considering the use of plastic syringes not manufactured in China if possible.

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

LEADER Eye Drops, Velocity Pharma LLC: Recall – Risk of Eye Infections 11/1/23
Cardinal Health recalled all lots of ophthalmic products supplied by Velocity Pharma LLC to the consumer level due to risk of eye infections. The recalled products are all over the counter products. A complete list can be found in the FDA posting of the company announcement.

Rugby Eye Drops, Velocity Pharma LLC: Recall – Risk of Eye Infections 11/1/23
The Harvard Drug Group doing business as Major Pharmaceutical and Rugby Pharmaceutical recalled all lots of Polyvinyl Alcohol 1.4% Lubricating Eye Drops (NDC 0536-1325-94) and Lubricating Tears Eye Drops (dextran/ hypromellose, 0.2%/0.3%; NDC 0536-1282-94) supplied by Velocity Pharma LLC to the consumer level due to risk of eye infections. The recalled products are over the counter products distributed nationwide starting 6/1/21.

0.9% Sodium Chloride Irrigation USP and Sterile Water for Irrigation USP, Nurse Assist LLC: Recall – Lack of Sterility Assurance 11/6/23

Nurse Assist LLC recalled 0.9% sodium chloride irrigation USP and sterile water for irrigation USP due to the potential for a lack of sterility. The recalled products were packaged in bottles, spray cans, and syringes and may have been packaged inside kits. A full list can be found on the FDA site.

Pressure Injectable Catheter Kits, Teleflex and Arrow International: Recall – Mislabeling 11/6/23

Teleflex and its subsidiary Arrow International recalled Pressure Injectable Catheter Kits due to mislabeling regarding the presence of chlorhexidine in the products. A list of recalled products can be found on the FDA site.

Cardinal Health Monoject Syringes, Cardinal Health: Recall – Incompatible with Syringe Pumps 11/14/23

Cardinal Health recalled syringes branded as "Cardinal Health Monoject syringes" as dimensional changes to these syringes make them incompatible for use with syringe pumps. The full list of recalled syringes can be found on the FDA site. See additional information in the drug safety communication above.

Novum IQ Syringe Pump, Baxter Healthcare: Recall – Potential Underdosing 11/15/23

Baxter Healthcare recalled the Novum IQ Syringe Pump due to a software error that may miscalculate volume after the pump detects an occlusion. Affected customers will be contacted with a software upgrade, but in the meantime the remaining fluid in the syringe after an infusion has been completed should be monitored and if the total dose was not delivered, users should reprogram the pump and deliver the remaining volume as necessary.

Sanxin Single Use Syringes, Fresenius Medical Care: Recall – Leakage 11/15/23

Fresenius Medical Care recalled Sanxin Single Use Sterile Syringes used during hemodialysis treatments following reports of blood or heparin leaking back or from the syringe. The recalled syringes are the 10 mL Luer lock syringe with needle (part number 15-10ML-0), the 10 mL Luer lock syringe without needle (part number 15-R010-0), and the 3 mL Luer lock syringe with needle (part number 15-03ML-0).

Lubricant and Multi-Symptom Eye Drops, Kilitch Healthcare India Limited: Recall – Safety 11/15/23

Kilitch Healthcare India Limited recalled all drops of eye drops with expiration dates from November 2023 to September 2025 due to unsanitary conditions found by FDA investigators. The products are sold by or labeled by Rugby, Target, Rite Aid, Leader (Cardinal Health), Velocity, CVS, and Walmart. A full list of products can be found on the FDA site.

Infusomat Space Volumetric Infusion Pump System, B. Braun Medical: Recall – Faulty Alarms 11/17/23

B. Braun Medical, Inc. recalled the Infusomat Space Volumetric Infusion Pump System (models 8713051U and 8713052U) due to faulty occlusion alarms which may sound when no occlusion exists causing the pump to stop delivery of medications.

KinderMed Pain & Fever, KinderFarms LLC: Recall – Risk of Acetaminophen Toxicity 11/17/23

KinderFarms, LLC recalled all lot of KinderMed Infants' Pain & Fever (oral suspension) and KinderMed Kids' Pain & Fever (oral suspension) due to acetaminophen instability. Ongoing testing of sample batches indicated some product lots were no longer in specification.

Vitrakvi (Larotrectinib) Oral Solution, Bayer: Recall – Microbial Contamination 11/21/23

Bayer recalled one lot of Vitrakvi (Larotrectinib) oral solution 20 mg/mL in 100 mL glass bottles (NDC 50419-392-01, Lot 2114228) due to microbial contamination identified as Penicillium brevicompactum observed during routine stability testing.

TING 2% Miconazole Nitrate Athlete's Foot Spray, Insight Pharmaceuticals: Recall - Benzene 11/24/23

Insight Pharmaceuticals recalled two lots of TING 2% Miconazole Nitrate Athlete's Foot Spray antifungal spray powder (lot 0H88645 and 0B88345) due to elevated levels of benzene.

VariSoft Infusion Sets, Unomedical A/S: Recall – Damage Resulting in Unexpected Disconnections 11/27/23
Unomedical A/S recalled VariSoft Infusion Sets due to damage in the connector piece caused during manufacturing that can lead to unexpected disconnections and interrupted insulin delivery. The following lot numbers are included in the recall: 5388367; 5388357; 5388371; 5388362; 5388368; 5388366; 5388372; 5388376.

Sandimmune (cyclosporine) Oral Solution, Novartis: Recall – Crystallization 11/27/23
Novartis recalled two lots of Sandimmune (cyclosporine) oral solution 100 mg/mL (NDC 0078-0110-22, lots FX001500 and FX001582) due to crystal formation observed in some bottles.

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	*Promoted Use*	*Undeclared Ingredient(s)*
Dr. Ergin's SugarMD Advanced Glucose Support	Blood glucose management	Glyburide, metformin
Himalayan Pain Relief Tea	Pain	Diclofenac, dexamethasone
Magnum XXL 9800 Capsules*	Sexual enhancement	Sildenafil
Neptune Fix	Improve brain function, treat anxiety, depression, opioid use disorder, pain	Tianeptine[1]
Notoginseng Formula Special Gout Granule	Gout, pain relief	Dexamethasone, diclofenac
The Rock by Noah's Wholesale*	Sexual enhancement	Sildenafil
Tepee Herbal Tea	Pain	Piroxicam

*recalled
[1]Tianeptine is not FDA approved; adverse events have included seizures and loss of consciousness.

New Product Shortages	*Date Initially Posted*
Cromolyn Sodium Concentrate	11/3/23

Brand Name or Sole Source Product Discontinuations/Withdrawals	*Date Posted*
Ofatumumab injection (Arzerra, Novartis): IV dosage form for chronic lymphocytic leukemia discontinued; ofatumumab remains available as Kesimpta for subcutaneous administration in multiple sclerosis	11/3/23

New Drug Approvals:	*Description (See Attached Drug Summaries)*	*Date Approved*
Fruquintinib / Fruzaqla / Takeda Pharmaceuticals America, Inc.	Kinase inhibitor indicated for the treatment of metastatic colorectal cancer in adults previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and if RAS wild-type and medically appropriate, an anti-EGFR therapy	11/8/23
ADAMTS13, recombinant-krhn / Adzynma / Takeda Pharmaceuticals USA, Inc.	Recombinant form of the ADAMTS13 enzyme for prophylactic or on demand enzyme replacement therapy in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura	11/9/23
Chikungunya vaccine, live / Ixchiq / Valneva USA Inc.	Vaccine for the prevention of disease caused by Chikungunya virus in adults	11/9/23
Taurolidine and heparin sodium / Defencath / CorMedix Inc.	Antimicrobial and anticoagulant for instillation into a central venous catheter to reduce the incidence of catheter-related bloodstream infections in adult patients with kidney failure receiving chronic hemodialysis	11/15/23

Repotrectinib / Augtyro / Bristol-Myers Squibb	Kinase inhibitor for the treatment of adults with locally advanced or metastatic ROS1-positive non-small cell lung cancer	11/15/23
Capivasertib / Truqap / AstraZeneca Pharmaceuticals LP	In combination with fulvestrant for adult patients with hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following progression on at least one endocrine-based regimen or within 12 months of completing adjuvant therapy	11/16/23
Efbemalenograstim alfa-vuxw / Ryzneuta / Evive Biotech	Leukocyte growth factor indicated to decrease the occurrence of infection from febrile neutropenia in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a high risk of febrile neutropenia	11/16/23
Nirogacestat / Ogsiveo / SpringWorks Therapeutics Inc.	Gamma secretase inhibitor for adults with progressing desmoid tumors requiring systemic treatment	11/27/23

New Indications:	***Description***	***Date Approved***
Bupivacaine liposome injectable suspension / Exparel / Pacira Pharmaceuticals	To produce postsurgical regional analgesia via a sciatic nerve block in the popliteal fossa or via an adductor canal block	11/9/23
Pembrolizumab / Keytruda / Merck & Co., Inc.	In combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic HER2 negative gastric or gastroesophageal junction adenocarcinoma	11/16/23
Enzalutamide / Xtandi / Astellas Pharma US, Inc.	For non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis	11/16/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Vonoprazan / Voquezna / Phathom Pharmaceuticals, Inc.	Tablets: 10 mg, 20 mg; for healing of erosive esophagitis and relief of heartburn associated with erosive esophagitis, to maintain healing of erosive esophagitis and relief of heartburn associated with erosive esophagitis, in combination with amoxicillin and clarithromycin for treatment of *Helicobacter pylori* infection, and in combination with amoxicillin for the treatment of *H. pylori* infection	11/1/23
Tirzepatide / Zepbound / Lilly	Injection: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL in single dose pens; adjunct to reduced-calorie diet and increased physical activity for chronic weight management in adults with BMI of 30 kg/m2 or greater (obesity) or 27 kg/m2 or greater (overweight) with at least one weight-related comorbid condition	11/8/23
Eltrombopag choline / Alvaiz / Teva	Tablets: 9 mg, 18 mg, 36 mg, 54 mg; for treatment of thrombocytopenia in patients 6 years and older with persistent or chronic immune thrombocytopenia and adults with chronic hepatitis C, and treatment of adults with sever aplastic anemia. Not substitutable with other eltrombopag products on a mg per mg basis.	11/29/23

Compiled by:
Terri Levien, Pharm.D.
Emily Hitt, Pharm.D., PGY1 Drug Information Resident

Drug Information Center
College of Pharmacy and Pharmaceutical Sciences
Washington State University
412 E. Spokane Falls Blvd.
Spokane, WA 99202-2131
(509) 358-7662
Pharmacy.druginfo@wsu.edu

Fruquintinib / Fruzaqla / Takeda Pharmaceuticals America, Inc.	
Generic Name / Brand Name / Company	Fruquintinib / Fruzaqla / Takeda Pharmaceuticals America, Inc.
Date of approval	11/8/23
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor; inhibits VEGFR-1, -2, and -3
Indication	Treatment of metastatic colorectal cancer in adults previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and if RAS wild-type and medically appropriate, an anti-EGFR therapy
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Capsules: 1 mg and 5 mg
Common Dose/sig	5 mg orally once daily for the first 21 days of each 28 day cycle; dose modifications advised for adverse reactions
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Fedratinib, Quizartinib
Clinical Use Evaluation	
Common Adverse Effects	≥20%: hypertension, palmar-plantar erythrodysesthesia, proteinuria, dysphonia, abdominal pain, diarrhea, asthenia
Severe Adverse Effects	Hemorrhage, GI perforation, pneumonia, sepsis, fatigue, hepatic failure/ encephalopathy, hypertension, stomatitis, abdominal pain, proteinuria
Severe Drug-Drug Interactions	Strong or moderate CYP3A inducers: avoid concomitant use
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver function tests, urine protein before initiation and periodically during treatment
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild hepatic impairment; has not been sufficiently studied in moderate hepatic impairment and use is not recommended in severe hepatic impairment. No dosage adjustment recommended in renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Labeling includes no contraindications. Warnings include hypertension, hemorrhagic events, infections, gastrointestinal perforation, hepatotoxicity, proteinuria, palmar-plantar erythrodysesthesia, posterior reversible encephalopathy syndrome, impaired wound healing, arterial thromboembolic events, allergic reactions to FD&C Yellow No. 5 (tartrazine) and No. 6 (sunset yellow FCF), and risk of fetal harm.
Special administration technique or considerations	Administered with or without food at approximately the same time each day; capsules should be swallowed whole.
Prepared by	Terri Levien
Source	Fruzaqla (fruquintinib) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2023.

ADAMTS13, recombinant-krhn / Adzynma / Takeda Pharmaceuticals USA, Inc.	
Generic Name / Brand Name / Company	ADAMTS13, recombinant-krhn / Adzynma / Takeda Pharmaceuticals USA, Inc.
Date of approval	11/9/23
Drug Class (Mechanism of Action if novel agent)	Enzyme replacement therapy; recombinant form of endogenous ADAMTS13, a plasma zinc metalloprotease that regulates the activity of von Willebrand factor
Indication	Prophylactic or on-demand enzyme replacement therapy in adults and pediatric patients with congenital thrombotic thrombocytopenic purpura
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Lyophilized powder in single-dose vials: ~500 or 1500 international units
Common Dose/sig	Prophylactic: 40 IU/kg every other week IV On-demand: 40 IU/kg on day 1, 20 IU/kg on day 2, 15 IU/kg on day 3 and beyond until 2 days after acute event is resolved
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Adzenys
Clinical Use Evaluation	
Common Adverse Effects	>5%: headache, diarrhea, migraine, abdominal pain, nausea, upper respiratory tract infection, dizziness, vomiting
Severe Adverse Effects	Allergic reactions
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None required
Used in Pediatric Areas	Indicated in pediatric and adult patients; clinical trial included patients aged 2 years and older. Weight-based dosing regimen is the same as for adults.
Renal or Hepatic Dosing	No dosage adjustments
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: life threatening hypersensitivity to product Warnings: hypersensitivity reactions, immunogenicity
Special administration technique or considerations	Vials are labeled with actual potency which should be used to calculate the administration dose and volume. Confirm product is within expiration date; do not use if expiration date has passed. Reconstitute using the supplied BAXJECT II Hi-Flow device following instructions in labeling. Use within 3 hours of reconstitution. Infuse product slowly IV at a rate of 2 to 4 mL per minute.
Prepared by	Terri Levien
Source	Adzynma (ADAMTS13, recombinant-krhn) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; November 2023.

Chikungunya vaccine, live / Ixchiq / Valneva USA Inc.	
Generic Name / Brand Name / Company	Chikungunya vaccine, live / Ixchiq / Valneva USA Inc.
Date of approval	11/9/23
Drug Class (Mechanism of Action if novel agent)	Vaccine
Indication	Prevention of disease caused by chikungunya virus in adults who are at increased risk of exposure to the virus
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Injection solution
Common Dose/sig	Single 0.5 mL IM dose
DEA Schedule	None
Date of market availability	Early 2024; Advisory Committee on Immunization Practices vote anticipated in February 2024
Similar Medication Names	Chickenpox vaccine
Clinical Use Evaluation	
Common Adverse Effects	>10%: injection site tenderness, headache, fatigue, myalgia, arthralgia, fever, nausea
Severe Adverse Effects	Severe or prolonged chikungunya-like adverse reactions, headache, fatigue, myalgia, arthralgia, fever, nausea, back pain
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None required
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No recommended modifications in renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: immunocompromised individuals, history of anaphylaxis to any vaccine component Warnings: immediate allergic reactions may occur; may cause severe or prolonged chikungunya-like adverse reactions; not known if vertical transmission of vaccine virus can occur or cause fetal or neonatal adverse reactions; syncope may occur with administration
Special administration technique or considerations	Reconstitution required with accompanying Sterile Water Diluent
Prepared by	Terri Levien
Source	Ixchiq (Chikungunya vaccine, live) [prescribing information]. Bethesda, MD: Valneva USA Inc.; November 2023

Taurolidine/heparin sodium / Defencath / CorMedix Inc.	
Generic Name / Brand Name / Company	Taurolidine and heparin sodium / Defencath / CorMedix Inc.
Date of approval	11/15/23
Drug Class (Mechanism of Action if novel agent)	Antimicrobial and anti-coagulant
Indication	For instillation into a central venous catheter to reduce the incidence of catheter-related bloodstream infections in adult patients with kidney failure receiving chronic hemodialysis
Comparative agent – Therapeutic interchange?	Heparin
Dosage forms/strengths.	Catheter lock solution in 3 mL and 5 mL single dose vials containing taurolidine 13.5 mg/mL and heparin 1,000 USP units/mL
Common Dose/sig	Instill catheter lock solution into each catheter lumen at the conclusion of each hemodialysis session
DEA Schedule	None
Date of market availability	First quarter 2024
Similar Medication Names	Heparin, Taurine,
Clinical Use Evaluation	
Common Adverse Effects	≥2%: hemodialysis catheter malfunction, hemorrhage/bleeding, nausea, vomiting, dizziness, musculoskeletal chest pain, thrombocytopenia
Severe Adverse Effects	None known
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None required
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Modifications not required for renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: known heparin-induced thrombocytopenia; known hypersensitivity to taurolidine, heparin, the citrate excipient, or pork products. Warnings: heparin-induced thrombocytopenia, hypersensitivity reactions Do not use as a catheter lock flush product. Safety and efficacy not established in populations other than adults with kidney failure receiving chronic hemodialysis through a central venous catheter.
Special administration technique or considerations	Use sufficient volume from the 3 mL or 5 mL vial to fill the catheter lumen. Aspirate the lock solution from the catheter and discard prior to the initiation of the next hemodialysis session.
Prepared by	Terri Levien
Source	Defencath (taurolidine and heparin sodium) [prescribing information]. Berkeley Heights, NJ: CorMedix Inc.; November 2023.

Repotrectinib / Augtyro / Bristol-Myers Squibb	
Generic Name / Brand Name / Company	Repotrectinib / Augtyro / Bristol-Myers Squibb
Date of approval	11/15/23
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor; inhibits proto-oncogene tyrosine kinase ROS1 and tropomyosin receptor tyrosine kinases TRKA, TRKB, and TRKC
Indication	Treatment of adults with locally advanced or metastatic ROS1-positive non-small cell lung cancer
Comparative agent – Therapeutic interchange?	Entrectinib
Dosage forms/strengths.	Capsules: 40 mg
Common Dose/sig	160 mg (4 capsules) orally once daily for 14 days, then 160 mg twice daily
DEA Schedule	None
Date of market availability	Mid-December 2023
Similar Medication Names	Auryxia
Clinical Use Evaluation	
Common Adverse Effects	≥20%: dizziness, dysgeusia, peripheral neuropathy, constipation, dyspnea, ataxia, fatigue, cognitive disorders, muscular weakness
Severe Adverse Effects	Dyspnea, dizziness, peripheral neuropathy, ataxia, cognitive disorders, nausea, diarrhea, vomiting, fatigue, edema, muscular weakness, myalgia, increased weight; decreased hemoglobin, lymphocytes, leukocytes, neutrophils, glucose; increased CPK, GGT, AST, ALT, sodium, alkaline phosphatase, glucose, urate
Severe Drug-Drug Interactions	Strong and moderate CYP3A inhibitors or inducers, P-gp inhibitors, hormonal contraceptive, and CYP3A substrates with narrow therapeutic range: avoid concomitant use
Severe Drug-Food Interactions	Grapefruit juice or grapefruit: avoid
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Uric acid at baseline and periodically during treatment; liver function tests including bilirubin at baseline, every 2 weeks for the first month, and as clinically indicated thereafter; CPK in patients with unexplained muscle pain, tenderness, or weakness
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild or moderate renal impairment or mild hepatic impairment. Recommended dose not established in patients with severe renal impairment or moderate or severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: central nervous system adverse reactions, interstitial lung disease/pneumonitis, hepatotoxicity, myalgia with CPK elevation, hyperuricemia, skeletal fractures, embryo-fetal toxicity
Special administration technique or considerations	Administer with or without food at approximately the same time each day. Swallow capsules whole; no not open or dissolve. Consult labeling for dose reductions for adverse reactions.
Prepared by	Terri Levien
Source	Augtyro (repotrectinib) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2023.

Capivasertib / Truqap / AstraZeneca Pharmaceuticals LP	
Generic Name / Brand Name / Company	Capivasertib / Truqap / AstraZeneca Pharmaceuticals LP
Date of approval	11/16/23
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor; inhibitor of serine/threonine kinase AKT (AKT1, AKT2, and AKT3) and phosphorylation of downstream AKT substrates
Indication	In combination with fulvestrant for patients with hormone receptor positive, HER2-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following progression on at least one endocrine-based regimen or within 12 months of completing adjuvant therapy
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Tablets: 160 mg and 200 mg
Common Dose/sig	400 mg orally twice daily for 4 days followed by 3 days off
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Capmatinib, Tukysa
Clinical Use Evaluation	
Common Adverse Effects	≥20%: diarrhea, cutaneous adverse reactions, nausea, fatigue, vomiting, stomatitis; increased glucose, triglycerides, creatinine; decreased lymphocytes, hemoglobin, leukocytes, neutrophils
Severe Adverse Effects	Severe hyperglycemia with ketoacidosis, diarrhea, erythema multiforme, palmar-plantar erythrodysesthesia, drug reaction with eosinophilia and systemic symptoms, nausea, vomiting, stomatitis, fatigue, renal injury, decreased lymphocytes, increased ALT, increased creatinine, decreased potassium
Severe Drug-Drug Interactions	Strong CYP3A inhibitors, strong and moderate CYP3A inducers: avoid use Moderate CYP3A inhibitors: reduce capivasertib dose
Severe Drug-Food Interactions	Grapefruit products
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Fasting blood glucose and HbA1c at baseline and at regular intervals during treatment
Used in Pediatric Areas	Efficacy and safety not established in pediatric patients
Renal or Hepatic Dosing	No dosing modification in mild to moderate renal impairment or mild hepatic impairment. Monitor patients with moderate hepatic impairment. Has not been studied in severe renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: severe hypersensitivity Warnings: hyperglycemia, diarrhea, cutaneous adverse reactions, fetal harm
Special administration technique or considerations	Taken with fulvestrant therapy. Administered capivasertib doses approximately 12 hours apart with or without food. Swallow tablets whole; do not take tablets that are broken, cracked or not intact. Consult prescribing information for dose modifications for adverse reactions or when used with CYP3A inhibitors.
Prepared by	Terri Levien
Source	Truqap (capivasertib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2023.

Efbemalenograstim alfa-vuxw / Ryzneuta / Evive Biotechnology	
Generic Name / Brand Name / Company	Efbemalenograstim alfa-vuxw / Ryzneuta / Evive Biotechnology
Date of approval	11/16/23
Drug Class (Mechanism of Action if novel agent)	Leukocyte growth factor; colony-stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors.
Indication	Decrease the occurrence of infection from febrile neutropenia in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a high risk of febrile neutropenia
Comparative agent – Therapeutic interchange?	Filgrastim, pegfilgrastim
Dosage forms/strengths.	20 mg/mL injection solution in a single-dose prefilled syringe.
Common Dose/sig	20 mg administered subcutaneously once per chemotherapy cycle. To be administered 24 hours after cytotoxic chemotherapy. Should not be administered between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
DEA Schedule	None
Date of market availability	Anticipated availability currently unknown
Similar Medication Names	Ryzodeg, Ryzolt, Ryzumvi, pegfilgrastim
Clinical Use Evaluation	
Common Adverse Effects	≥10%: nausea, anemia, thrombocytopenia
Severe Adverse Effects	Splenic rupture, acute respiratory distress syndrome, hypersensitivity reactions, sickle cell crisis, leukocytosis, thrombocytopenia, capillary leak syndrome
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	WBC/CBC counts, platelet counts
Used in Pediatric Areas	Safety and effectiveness in pediatric patients have not been established.
Renal or Hepatic Dosing	Impact of renal and hepatic impairment on pharmacokinetics of elbemalenograstim alfa is unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Patients with a history of serious allergic reactions to granulocyte stimulating factors. Warnings: splenic rupture, acute respiratory distress syndrome, hypersensitivity reactions, sickle cell crisis in patients with sickle cell disorders, leukocytosis, thrombocytopenia, capillary leak syndrome, stimulatory effects on tumor growth in malignant cells, myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) in patients with breast and lung cancer, aortitis
Special administration technique or considerations	To be administered by a healthcare professional; those with latex allergies should not administer the product. Allow product to reach room temperature before administration. Deliver entire contents of the prefilled syringe. Inject into abdomen, back or side of upper arms or thighs. Rotate injection sites.
Prepared by	Emily Hitt
Source	Ryzneuta (efbemalenograstim alfa) [prescribing information].

Nirogacestat / Ogsiveo / SpringWorks Therapeutics Inc.	
Generic Name / Brand Name / Company	Nirogacestat / Ogsiveo / SpringWorks Therapeutics Inc.
Date of approval	November 27, 2023
Drug Class (Mechanism of Action if novel agent)	Gamma secretase inhibitor
Indication	Use in adult patients with progressing desmoid tumors requiring systemic treatment
Comparative agent – Therapeutic interchange?	Combination chemotherapy
Dosage forms/strengths.	Tablets: 50 mg
Common Dose/sig	150 mg (3 tablets) orally twice daily
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Nirsevimab, Oxsoralen
Clinical Use Evaluation	
Common Adverse Effects	>15%: diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection, dyspnea; decreased phosphate, potassium; increased urine glucose, urine protein, AST, ALT
Severe Adverse Effects	Diarrhea, nausea, stomatitis, abdominal pain, rash, fatigue, hepatotoxicity, decreased potassium
Severe Drug-Drug Interactions	Strong or moderate CYP3A inhibitors or inducers: avoid concomitant use Gastric acid reducing agents: avoid use with proton pump inhibitors or H2 antagonists; stagger use with antacids
Severe Drug-Food Interactions	Starfruit, Seville oranges, grapefruit, and juice from these fruits
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy test prior to initiating in females of reproductive potential; monitor phosphate, potassium, AST, and ALT regularly
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients; potential for development of epiphyseal disorder with use
Renal or Hepatic Dosing	No dose modifications recommended; pharmacokinetics not altered in mild or moderate renal impairment, exposure increased in moderate hepatic impairment and not studied in severe impairment; withhold if ALT or AST increased
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: severe diarrhea, ovarian toxicity and impaired fertility, hepatotoxicity, non-melanoma skin cancers, electrolyte abnormalities, fetal harm
Special administration technique or considerations	Administer with or without food. Swallow tablets whole. Dose modifications recommended for severe adverse reactions.
Prepared by	Terri Levien
Source	Ogsiveo (nirogacestat) [prescribing information]. Stamford, CT: SpringWorks Therapeutics, Inc.; November 2023