WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 5/1/23 – 5/31/23

FDA Drug Safety Communications & Drug Information Updates:

FDA Takes Additional Steps to Advance Decentralized Clinical Trials 5/2/23

The FDA is taking additional steps to support the use of decentralized clinical trials (DCTs) for drugs, biologics, and devices, where some or all the trial activities occur at locations that are not traditional location sites. The agency released a new draft guidance with recommendations for sponsors, investigators, and other stakeholders regarding the implementation of DCTs that will allow some or all trial-related activities to take place at trial participants' homes, or other convenient locations instead of having them visit research sites.

Updates to Labeling of Prescription Stimulants Required 5/11/23

The FDA is requiring updates to the labeling of amphetamine and methylphenidate products to update and standardize the information regarding risks. The required changes will address misuse and abuse, addiction, and overdose information, as well as consistent language instructing patients to never share their prescription stimulants with anyone. Health care professionals are reminded to educate regarding risks and regularly assess and monitor for signs of nonmedical use, addiction, and potential diversion.

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

Over-the-Counter Advil Products, Family Dollar: Recall – Stored Outside Labeled Requirements 5/4/23

Family Dollar recalled certain OTC Advil products that were stored and shipped to certain stores from approximately June 1, 2022 through March 31, 2023 due to the product being stored by Family Dollar outside of labeled temperature requirements. The complete list of recalled Advil products can be found on the FDA site.

SD Biosensor Pilot COVID-19 At-Home Test: Recall and Safety Communication – Avoid Use 5/4/23

The FDA warned consumers and health care providers to stop using and throw out certain lots of the SD Biosensor, Inc. Pilot COVID-19 At-Home Tests distributed by Roche Diagnostics due to concerns of bacterial contamination in the liquid solution provided with the kit. Direct contact with the liquid may pose safety concerns and contamination may impact the tests' performance. The recalled kits should be disposed of in the trash; the liquid should not be poured down the drain. A full list of recalled lot numbers can be found on the FDA site.

G-Supress DX Pediatric Drops, Novis PR LLC: Recall - Incorrect Packaging 5/19/23

Novis PR LLC recalled one lot of over-the-counter G-Suppress DX Pediatric Drops (lot D20911, exp 10/25) due to some cartons containing incorrect product. On 5/15/23 the company announced that several cartons of the pediatric cough drops were found to contain an anesthetic/analgesic that was not a brand of Novis PR LLC. The anesthetic/analgesic contained 60% ethyl alcohol and 5% benzocaine, thus putting infants and young children exposed to the product at risk of alcohol toxicity and methemoglobinemia.

Plum Infusion Systems Replacement Batteries, ICU Medical: Recall – Diminished Battery Life 5/22/23

ICU Medical recalled the replacement batteries for Plum 360 (battery SUB0000864) and Plum A+ and Plum A+3 (battery SUB0000594) Infusion Systems due to a manufacturing defect that substantially diminished battery life. If the infusion pump is running on battery power without AC power backup, the system may shut down an ongoing infusion and power down sooner than expected. These infusion systems are used to deliver fluids, blood, and medications. These pumps should be kept plugged in whenever possible and ensure the battery is fully charged before disconnecting from AC power (eg, to transport a patient). A backup pump should be available during all infusions, and particularly when infusing critical medications. Customers will be contacted by ICU Medical to schedule battery replacement when batteries are available.

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) or Contaminants***
Diamond Girl Lite	Sexual enhancement	Sildenafil
Fast-Act Rheuma Capsule	Joint pain and rheumatoid arthritis	Prednisone-21-acetate and piroxicam
Hard Steel 300K	Sexual enhancement	Tadalafil
Honey Girl	Sexual enhancement	Sildenafil
Infinity	Sexual enhancement	Sildenafil
Infinity 10K	Sexual enhancement	Sildenafil and tadalafil
MEGA 7G 700000	Sexual enhancement	Sildenafil and acetaminophen
MEGA 9K 800000	Sexual enhancement	Sildenafil and tadalafil
Meta Forte	Sexual enhancement	Sildenafil and tadalafil
Mr. Strong Guy Honey for Him	Sexual enhancement	Sildenafil
Natural MiracleZEN GOLD 60000	Sexual enhancement	Sildenafil and tadalafil
New Fast-Act Rheumatism Capsule	Joint pain and arthritis	Indomethacin
Phentamene XT	Weight loss	DMAA (1,3-dimethylamylamine or methylhexanamine)
Platinum 69000 Rhino 69	Sexual enhancement	Sildenafil
Power Plus Desire	Sexual enhancement	Sildenafil
Rhino 7S Type F3 7000	Sexual enhancement	Sildenafil and acetaminophen
Special Edition Platinum 10K	Sexual enhancement	Tadalafil and vardenafil
UA-Block	Joint pain and inflammation, pain from gout, liver detoxification	Indomethacin
V=GRA GOLD 500 mg	Sexual enhancement	Sildenafil
XXX Zone 40K	Sexual enhancement	Sildenafil and tadalafil

*recalled

[1]DMAA often referred to as “geranium extract” can elevate blood pressure leading to cardiovascular adverse effects.

New Product Shortages	***Date Initially Posted***
Isoniazid tablets	5/17/23
Lidocaine hydrochloride (viscous) oral topical solution	5/18/23

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Voriconazole 200 mg tablets (Vfend, Pfizer); other formulations and generics remain available	5/10/23
Estramustine phosphate sodium capsules (Emcyt, Pfizer); supplies predicted to be exhausted in January 2024. Not available from other manufacturers.	5/18/23
Propafenone hydrochloride extended-release capsules (Rythmol SR, GlaxoSmithKline); generics remain available	5/19/23
Doxercalciferol capsules (Genzyme brand and Winthrop authorized generic, Sanofi-Aventis); other generics remain available	5/19/23
Ibrutinib 560 mg tablets (Imbruvica, AbbVie); all other strengths and formulations remain available	5/22/23

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Respiratory syncytial virus vaccine/ Arexvy / GlaxoSmithKline	Adjuvanted vaccine for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older	5/3/23
Pegunigalsidase alfa-IWXJ / Elfabrio / Chiesi USA, Inc.	A hydrolytic lysosomal neutral glycosphingolipid-specific enzyme for the treatment of adults with confirmed Fabry disease	5/9/23
Fezolinetant / Veozah / Astellas	Neurokinin 3 receptor antagonist for the treatment of moderate to severe vasomotor symptoms due to menopause	5/12/23
Perfluorohexyloctane / Miebo / Bausch and Lomb Inc	Semi fluorinated alkane for the treatment of both the signs and symptoms of dry eye disease	5/18/23
Beremagene geperpavec / Vyjuvek/ Krystal Biotech, Inc.	Gene therapy for the treatment of wounds in patients 6 months and older with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene	5/19/23
Epcoritamab-bysp / Epkinly / Genmab	Bispecific CD20-directed CD3 T-cell engager for the treatment of relapsed or refractory diffuse large B-cell lymphoma	5/19/23
Sulbactam; durlobactam / Xacduro/ Entasis	Injectable treatment for hospital-acquired and ventilator associated bacterial pneumonia	5/23/23
Ritonavir, Nirmatrelvir / Paxlovid / Pfizer	Combination of SARS-CoV-2 main protease inhibitor and HIV-1/CYP3A inhibitor for the treatment of mild-moderate COVID-19 who are at high risk of progression.	5/25/23
Respiratory syncytial virus vaccine/ Abrysvo / Pfizer Inc.	A vaccine for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older	5/31/23

New Indications:	***Description***	***Date Approved***
Ivacaftor / Kalydeco / Vertex Pharmaceuticals	Indication expanded to include treatment of cystic fibrosis in patients 1 month to less than 4 months who have at least one mutation in the CFTR gene that is responsive to ivacaftor	5/3/23
Dapagliflozin / Farxiga / AstraZeneca Pharmaceuticals	To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure	5/8/23
Brexipiprazole / Rexulti / Otsuka	Treatment of agitation associated with dementia due to Alzheimer's disease	5/10/23
Ibuprofen / Caldolor / Cumberland Pharmaceuticals	Indication expanded to include use in infants 3 months and older	5/11/23
Fluticasone furoate and vilanterol/ Breo Ellipta / GlaxoSmithKline	Indication expanded for 100/25 mcg strength to include maintenance treatment of asthma in patients 12 to 17 years old	5/12/23
Escitalopram / Lexapro / AbbVie	Indication expanded for tablets and oral solution to include generalized anxiety disorder in patients 7 to 17 years of age	5/12/23
Upadactinib / Rinvoq / AbbVie	Treatment of moderately to severely active Crohn's disease in adults who failed one or more tumor necrosis factor blockers	5/18/23
Avapritinib / Ayvakit / Blueprint Medicines Corporation	Treatment of adult patients with indolent systemic mastocytosis	5/22/23
Iopromide / Ultravist / Bayer HealthCare Pharmaceuticals Inc.	Contrast mammography to visualize known or suspected lesions of the breast in adults, as an adjunct following mammography and/or ultrasound	5/25/23
Ferric carboxymaltose / Injectafer/ American Regent, Inc.	Treatment of iron deficiency in adult patients with heart failure and New York Heart Association Class II/III to improve exercise capacity	5/31/23
Olaparib / Lynparza / AstraZeneca Pharmaceuticals LP	Use in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer	5/31/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Lacosamide / Motpoly XR / Aucta Pharmaceuticals, Inc.	Extended-release capsules: 100 mg, 150 mg, 200 mg; for the treatment of partial-onset seizures in adults and pediatric patients weighing at least 50 kg	5/4/23
Tropicamide and phenylephrine HCl / Mydcombi / Eyenovia Inc.	Ophthalmic spray: tropicamide 1%/phenylephrine HCl 2.5%; to induce mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired	5/5/23
Zolpidem tartrate / Almatica Pharma	Capsules: 7.5 mg; treatment of insomnia characterized by difficulties with sleep initiation in adults younger than 65 years of age	5/9/23
Fluticasone furoate and vilanterol / Breo Ellipta / GlaxoSmithKline	Inhalation powder: 50/25 mcg; new strength indicated for maintenance treatment of asthma in patients 5 to 11 years and	5/12/23
Nalmefene / Opvee / Opiant	Nasal spray: 2.7 mg nalmefene per device indicated for the emergency treatment of opioid overdose	5/22/23
Buprenorphine / Brixadi / Braeburn	Injection, extended release; subcutaneous: 8 mg, 16 mg, 24 mg, 32 mg, 64 mg, 96 mg, 128 mg injections for moderate to severe opioid use disorder	5/23/23
Adalimumab / Yuflyma / Celltrion	New active ingredient: Adalimumab-AATY 40mg/0.4mL, now approved as the ninth Adalimumab biosimilar	5/24/23
Cyclosporine / Vevye / Novaliq GmbH	Ophthalmic solution 0.1%: for the treatment of dry eye disease	5/30/23

Compiled by:

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Respiratory syncytial virus vaccine, adjuvanted / Arexvy / GlaxoSmithKline	
Generic Name / Brand Name / Company	Respiratory syncytial virus vaccine, adjuvanted / Arexvy / GlaxoSmithKline
Date of approval	5/3/23
Drug Class (Mechanism of Action if novel agent)	Inactivated (viral) vaccine, recombinant
Indication	Prevention of lower respiratory tract disease caused by respiratory syncytial virus in individuals 60 years of age and older
Comparative agent – Therapeutic interchange?	RSV vaccine (Abrysvo, Pfizer)
Dosage forms/strengths.	Suspension for injection in a single-dose vial to be reconstituted with the accompanying adjuvant suspension
Common Dose/sig	0.5 mL as an intramuscular injection
DEA Schedule	N/A
Date of market availability	Availability anticipated fall 2023
Similar Medication Names	Aredia, Arestin, Ubrelvy
Clinical Use Evaluation	
Common Adverse Effects	>10%: injection site pain, fatigue, myalgia, headache, arthralgia
Severe Adverse Effects	Pain, redness, swelling, fatigue, myalgia, headache, arthralgia, atrial fibrillation, Guillain-Barre 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.	None
Used in Pediatric Areas	Current data from animal model suggests unsafe for use in individuals younger than 2 years of age due to increased risk of enhanced respiratory disease; safety and efficacy not established in subjects 2 through 17 years
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications - History of severe allergic reaction (anaphylaxis) to any component of the vaccine Warnings and precautions - Appropriate medical treatment and supervision should be available to manage possible anaphylactic reactions - Immunocompromised patients or patients receiving immunosuppressive therapy may have a diminished immune response - Syncope may occur
Special administration technique or considerations	Should be administered immediately after reconstitution, or store protected from light in the refrigerator between 2°C and 8°C or at room temperature and use within 4 hours.
Prepared by	Kenric Aalund-Nelson
Source	*Arexvy* (respiratory syncytial virus vaccine, adjuvanted) [prescribing information]. Durham, NC: GlaxoSmithKline Biologics; May 2023

Pegunigalsidase alfa-IWXJ / Elfabrio / Chiesi USA, Inc.	
Generic Name / Brand Name / Company	Pegunigalsidase alfa-IWXJ / Elfabrio / Chiesi USA, Inc.
Date of approval	5/9/23
Drug Class (Mechanism of Action if novel agent)	Enzyme, Metabolic
Indication	Treatment of adults with confirmed Fabry disease
Comparative agent – Therapeutic interchange?	Agalsidase beta (Fabrazyme)
Dosage forms/strengths.	Injection: 20 mg/10 mL solution in single-dose vial
Common Dose/sig	1 mg/kg (actual body weight) administered via IV infusion every 2 weeks
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Elfolate
Clinical Use Evaluation	
Common Adverse Effects	≥15%: infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.
Severe Adverse Effects	Anaphylaxis, infusion-associated reactions
Severe Drug-Drug Interactions	Patients that received previous enzyme replacement therapy have an increased risk of carrying pre-existing anti-drug antibodies (ADA). Pre-existing ADA may reduce plasma concentrations of pegunigalsidase alfa thus reducing its efficacy. Pre-existing ADA also increase the risk of hypersensitivity reactions with pegunigalsidase alfa.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No adjustments recommended
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: None Warnings & precautions: - Hypersensitivity reactions including anaphylaxis - Infusion-associated reactions - Membranoproliferative glomerulonephritis reported in 1 patient
Special administration technique or considerations	- Anaphylaxis has occurred during administration; appropriate medical support measures including cardiopulmonary resuscitation equipment should be readily available during administration. In the event of a severe hypersensitivity or infusion-associated reaction, immediately discontinue infusion. In a mild to moderate reaction temporarily hold infusion or slow infusion rate. - Pretreatment with antihistamines, antipyretics, and/or corticosteroids should be considered; a desensitization procedure may be considered in patients experiencing severe hypersensitivity reactions. - Infuse using an in-line low protein-binding, 0.1-micron filter. Consult prescribing information for recommended infusion rate based on treatment experience and body weight. Home infusion under supervision of a healthcare provider may be considered once an infusion duration is reached that is well tolerated.
Prepared by	Kenric Aalund-Nelson
Source	*Elfabrio* (Pegunigalsidase alfa-IWXJ) [prescribing information] Cary, NC: Chiesi USA, Inc.; May 2023

Fezolinetant / Veozah / Astellas	
Generic Name / Brand Name / Company	Fezolinetant / Veozah / Astellas
Date of approval	5/12/23
Drug Class (Mechanism of Action if novel agent)	Neurokinin 3 receptor antagonist
Indication	Treatment of moderate to severe vasomotor symptoms due to menopause
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Tablets: 45 mg
Common Dose/sig	One 45 mg tablet orally once daily with or without food
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Fesoterodine, Fezolin
Clinical Use Evaluation	
Common Adverse Effects	≥2%: abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Contraindicated with CYP1A2 inhibitors: fezolinetant is a CYP1A2 substrate and concomitant use with drugs that are weak, moderate, or strong CYP1A2 inhibitors can increase the plasma Cmax and AUC of fezolinetant
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Perform baseline bloodwork to evaluate for hepatic function and injury [including serum alanine aminotransferase (ALT), serum aspartate aminotransferase (AST), and serum bilirubin (total and direct)] before initiating treatment. Perform follow-up bloodwork at 3 months, 6 months, and 9 months after initiation of therapy and when symptoms (such as nausea, vomiting, or yellowing of the skin or eyes) suggest liver injury.
Used in Pediatric Areas	Efficacy and safety not established
Renal or Hepatic Dosing	Contraindicated in patients with severe (eGFR <30 mL/min/1.73 m2) renal impairment or end stage renal disease (eGFR <15 mL/min/1.73 m2). No dosage adjustment for mild to moderate renal impairment. Contraindicated if patient has cirrhosis. Exposure increased in Child-Pugh Class A or B hepatic impairment; not studied in Child-Pugh Class C.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: - Known cirrhosis - Severe renal impairment or end-stage renal disease - Concomitant use with CYP1a2 inhibitors Warnings and precautions - Hepatic transaminase elevation
Special administration technique or considerations	Administer at about the same time each day.
Prepared by	Kenric Aalund-Nelson
Source	*Veozah* (Fezolinetant) [prescribing information] Northbrook, IL: Astellas Pharma US, Inc.; May 2023

Beremagene geperpavec / Vyjuvek / Krystal Biotech, Inc.	
Generic Name / Brand Name / Company	Beremagene geperpavec / Vyjuvek / Krystal Biotech, Inc.
Date of approval	5/19/23
Drug Class (Mechanism of Action if novel agent)	Gene therapy, herpes simplex virus type 1 vector
Indication	Treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Biological suspension, mixed in excipient gel: 1 mL (extractable volume) in single-dose vial at concentration of $5x10^9$ PFU/mL
Common Dose/sig	Apply gel to selected wound(s) in droplets spaced evenly within the wound, approximately 1 cm by 1 cm apart in a grid pattern, once a week. Maximum weekly volume 0.8 mL for patients 6 months to less than 3 year and 1.6 mL for patients 3 years and older.
DEA Schedule	N/A
Date of market availability	3rd quarter 2023
Similar Medication Names	None identified
Clinical Use Evaluation	
Common Adverse Effects	>5%: itching, chills, redness, rash, cough, runny nose
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
Used in Pediatric Areas	Safety and efficacy established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings: accidental exposure to vector
Special administration technique or considerations	- Apply gel to wounds until they are closed before selecting new wound(s) to treat. Prioritize weekly treatment to previously treated wounds if they re-open. - Only a healthcare provider should apply the gel, either at a professional setting or the home setting. The gel should be prepared at the pharmacy by mixing the biological suspension into the excipient gel for immediate use within 8 hours. A non-adherent hydrophobic dressing slightly larger than the wound size should be placed over the treated wound and not be changed for 24 hours after gel application. - Individuals who are pregnant should not prepare or apply the gel and should avoid contact with the treated wounds or dressings from the wounds. - Clean all surfaces that may have come into contact with the gel including bandages from first dressing change and treat all spills with a virucidal agent (eg, 70% isopropyl alcohol) and dispose all materials into a biohazard bag or container.
Prepared by	Terri Levien
Source	Vyjuvek (beremagene geperpavec-svdt) [prescribing information]. Pittsburgh, PA: Krystal Biotech, Inc. May 2023.

<table>
<tr><th colspan="2">Epcoritamab-bysp / Epkinly / Genmab</th></tr>
<tr><td>Generic Name / Brand Name / Company</td><td>Epcoritamab-bysp / Epkinly / Genmab</td></tr>
<tr><td>Date of approval</td><td>5/19/23</td></tr>
<tr><td>Drug Class (Mechanism of Action if novel agent)</td><td>Bispecific CD20-directed CD3 T-cell engager</td></tr>
<tr><td>Indication</td><td>Treatment of adult patients with relapsed or diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL originating from indolent lymphoma, and high grade B-cell lymphoma after two or more lines of systemic therapy.</td></tr>
<tr><td>Comparative agent – Therapeutic interchange?</td><td>None</td></tr>
<tr><td>Dosage forms/strengths.</td><td>Injection: 4 mg/0.8 mL in a single-dose vial. Dilute prior to use.
Injection: 48 mg/0.8 mL in a single-dose vial.</td></tr>
<tr><td>Common Dose/sig</td><td>For subcutaneous injection only. Administered in 28-day cycles.
<table>
<tr><th>Cycle</th><th>Day in cycle</th><th colspan="2">Dose</th></tr>
<tr><td rowspan="4">Cycle 1</td><td>1</td><td>Step-up dose 1</td><td>0.16 mg</td></tr>
<tr><td>8</td><td>Step-up dose 2</td><td>0.8 mg</td></tr>
<tr><td>15</td><td>First full dose</td><td>48 mg</td></tr>
<tr><td>22</td><td colspan="2">48 mg</td></tr>
<tr><td>Cycles 2 and 3</td><td>1, 8, 15, and 22</td><td colspan="2">48 mg</td></tr>
<tr><td>Cycles 4 to 9</td><td>1 and 15</td><td colspan="2">48 mg</td></tr>
<tr><td>Cycle 10 +</td><td>1</td><td colspan="2">48 mg</td></tr>
</table></td></tr>
<tr><td>DEA Schedule</td><td>N/A</td></tr>
<tr><td>Date of market availability</td><td>Available</td></tr>
<tr><td>Similar Medication Names</td><td>Epinephrine, Epidiolex, Epclusa</td></tr>
<tr><td colspan="2">Clinical Use Evaluation</td></tr>
<tr><td>Common Adverse Effects</td><td>≥20%: cytokine release syndrome, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea</td></tr>
<tr><td>Severe Adverse Effects</td><td>Cytokine release syndrome, cytopenias, Immune Effector Cell-Associated Neurotoxicity Syndrome</td></tr>
<tr><td>Severe Drug-Drug Interactions</td><td>Can cause release of cytokines that suppress activity of CYP enzymes, resulting in increased exposure of CYP substrates and toxic levels of drug concentrations.</td></tr>
<tr><td>Severe Drug-Food Interactions</td><td>N/A</td></tr>
<tr><td>Important Labs Values to assess prior to order entry or at point of clinical follow up.</td><td>Monitor complete blood counts throughout treatment.</td></tr>
<tr><td>Used in Pediatric Areas</td><td>Safety and efficacy not established</td></tr>
<tr><td>Renal or Hepatic Dosing</td><td>None dosage adjustments recommended</td></tr>
<tr><td>Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized</td><td>Contraindications: None
Warnings & precautions:
- Cytokine release syndrome
- Immune effector cell-associated neurotoxicity syndrome
- Infections: monitor and provide Pneumocystis jirovecci pneumonia and herpes virus prophylaxis
- Cytopenia
- Embryo-fetal toxicity</td></tr>
<tr><td>Special administration technique or considerations</td><td>Premedicate before each dose. Administer subcutaneously into the lower part of the abdomen (preferred) or the thigh. Changing injection site from the left to right side or vice versa is recommended.</td></tr>
<tr><td>Prepared by</td><td>Kenric Aalund-Nelson</td></tr>
<tr><td>Source</td><td>Epkinly (Epcoritamab-bysp) [prescribing information] Plainsboro, NJ: Genmab US, Inc; May 2023</td></tr>
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Perfluorohexyloctane / Miebo / Bausch and Lomb Inc	
Generic Name / Brand Name / Company	Perfluorohexyloctane / Miebo / Bausch and Lomb Inc
Date of approval	5/22/23
Drug Class (Mechanism of Action if novel agent)	A semifluorinated alkane that forms a monolayer at the air-liquid interface of the tear film which can reduce evaporation.
Indication	Treatment of the signs and symptoms of dry eye disease
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Ophthalmic solution: 100% perfluorohexyloctane
Common Dose/sig	Instill one drop four times daily into affected eye(s)
DEA Schedule	N/A
Date of market availability	Second half of 2023
Similar Medication Names	Mibelas, Moban, Mobic, Perflutren
Clinical Use Evaluation	
Common Adverse Effects	Blurred vision (1-3%)
Severe Adverse Effects	None
Severe Drug-Drug Interactions	None
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none
Special administration technique or considerations	Contact lenses should be removed prior to and for at least 30 minutes after the administration of perfluorohexyloctane drops
Prepared by	Kenric Aalund-Nelson
Source	*Miebo* (Perfluorohexyloctane) [prescribing information] Bridgewater, NJ: Bausch & Lomb Inc.; May 2023

Sulbactam and durlobactam / Xacduro / Entasis	
Generic Name / Brand Name / Company	Sulbactam and durlobactam / Xacduro / Entasis
Date of approval	5/23/23
Drug Class (Mechanism of Action if novel agent)	Antibacterial. Sulbactam is a beta-lactam antibacterial and Ambler Class A serine beta-lactamase inhibitor that has bactericidal activity due to its inhibition of *Acinetobacter baumannii-calcoaceticus* complex (ABC) penicillin-binding proteins PBP1 and PBP3, essential enzymes required for bacterial cell wall synthesis. Durlobactam is a diazabicyclooctane non-beta-lactam, beta-lactamase inhibitor, that protects sulbactam from degradation by certain serine-beta-lactamases. Durlobactam alone does not have antibacterial activity against ABC isolates.
Indication	Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex in adults
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Kit containing 1 vial sulbactam 1 g and 2 vials durlobactam 0.5 g
Common Dose/sig	1 g sulbactam and 1 g durlobactam IV every 6 hours for 7 to 14 days in patients with creatinine clearance (CrCl) of 45 to 129 mL/min.
DEA Schedule	N/A
Date of market availability	Late 2023
Similar Medication Names	Sulbactam, Xaciato
Clinical Use Evaluation	
Common Adverse Effects	>10%: liver test abnormalities, diarrhea, anemia, and hypokalemia
Severe Adverse Effects	Anaphylaxis
Severe Drug-Drug Interactions	Organic Anion Transporter 1 (OAT1) Inhibitors: Concomitant administration with OAT1 inhibitors may increase plasma concentrations of sulbactam; concomitant administration not recommended
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Creatinine clearance
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	Adjust frequency based on renal function: CrCl > 130: every 4 hours CrCl 45 to 129: every 6 hours CrCl 30 to 44: every 8 hours CrCl 15 to 29: every 12 hours CrCl < 15: for new start every 12 hours for first 3 doses (0, 12, and 24 hrs) then every 24 hours; if CrCl declines to < 15 mL/min then every 24 hrs No dosage adjustments recommended in hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Known history of severe hypersensitivity to the product components or other beta-lactam antibacterial drugs. Warnings and Precautions: - Hypersensitivity reactions - *Clostridioides difficile* associated diarrhea (CDAD)
Special administration technique or considerations	Bring to ambient room temperature over 15 to 30 min prior to infusion. Administer all doses by IV infusion over 3 hours.
Prepared by	Kenric Aalund-Nelson
Source	*Xacduro* (Sulbactam, Durlobactam) [prescribing information] Waltham, MA: Enstatsis Therapeutics Inc.; May 2023

Ritonavir and Nirmatrelvir / Paxlovid / Pfizer	
Generic Name / Brand Name / Company	Ritonavir and Nirmatrelvir / Paxlovid / Pfizer
Date of approval	5/25/23
Drug Class (Mechanism of Action if novel agent)	Antiviral
Indication	For the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Co-packaged nirmatrelvir 150 mg tablets + ritonavir 100 mg tablets
Common Dose/sig	300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) with all 3 tablets taken together orally twice daily for 5 days.
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Paxil, Paxel
Clinical Use Evaluation	
Common Adverse Effects	≥1%: dysgeusia and diarrhea
Severe Adverse Effects	Anaphylaxis, toxic epidermal necrolysis, Stevens-Johnson syndrome
Severe Drug-Drug Interactions	CYP3A substrates and inducers Extensive interactions: review all medications prior to prescribing
Severe Drug-Food Interactions	N/A
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Renal function
Used in Pediatric Areas	The optimal dose has not been established for pediatric patients
Renal or Hepatic Dosing	No dosage adjustment is recommended in patients with mild renal impairment (eGFR ≥60 to <90 mL/min). Reduce the Paxlovid dosage in patients with moderate renal impairment (eGFR ≥30 to <60 mL/min) to nirmatrelvir 150 mg and ritonavir 100 mg taken together twice daily for 5 days. Use not recommended in patient with severe renal impairment (eGFR <30 mL/min) or patients with end stage renal disease (eGFR <15 mL/min) receiving dialysis until more data is available. No modifications to dose for patients with mild or moderate hepatic impairment. Not recommended for use in patients with severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: - History of clinically significant hypersensitivity reactions to components of the product - Drugs that are primarily metabolized by CYP3A (see package insert for complete list) Warnings and precautions: - Risk of serious adverse reactions due to drug interactions - Hypersensitivity reactions - Hepatotoxicity - Risk of HIV-1 resistance development
Special administration technique or considerations	Nirmatrelvir tablets must be taken with ritonavir tablets
Prepared by	Kenric Aalund-Nelson
Source	*Paxlovid* (Nirmatrelvir; Ritonavir) [prescribing information] New York, NY: Pfizer Inc.; May 2023

Respiratory syncytial virus vaccine / Abrysvo / Pfizer Inc.	
Generic Name / Brand Name / Company	Respiratory syncytial virus vaccine / Abrysvo / Pfizer Inc.
Date of approval	5/31/23
Drug Class (Mechanism of Action if novel agent)	Inactivated (viral) vaccine, recombinant
Indication	Prevention of lower respiratory tract disease caused by respiratory syncytial virus in individuals 60 years of age and older
Comparative agent – Therapeutic interchange?	RSV vaccine, adjuvanted (Arexvy, GlaxoSmithKline)
Dosage forms/strengths.	Kit containing vial of lyophilized antigen and prefilled diluent syringe
Common Dose/sig	0.5 mL as an intramuscular injection
DEA Schedule	N/A
Date of market availability	Availability anticipated fall 2023
Similar Medication Names	Abreva
Clinical Use Evaluation	
Common Adverse Effects	>10%: fatigue, headache, pain at injection site, muscle pain
Severe Adverse Effects	Injection site pain, redness, swelling, fatigue, headache, muscle pain, joint pain, diarrhea, Guillain-Barre 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.	None
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications - History of severe allergic reaction (anaphylaxis) to any component of the vaccine Warnings and precautions - Appropriate medical treatment and supervision should be available to manage possible anaphylactic reactions - Immunocompromised patients or patients receiving immunosuppressive therapy may have a diminished immune response - Syncope may occur
Special administration technique or considerations	Should be administered immediately after reconstitution, or store at room temperature and use within 4 hours
Prepared by	Terri Levien
Source	Abrysvo (respiratory syncytial virus vaccine) [prescribing information]. New York, NY: Pfizer Inc.; May 2023.