WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 10/1/23 – 10/31/23

FDA Drug Safety Communications & Drug Information Updates:

Updated Novavax COVID-19 Vaccine Authorized 10/3/23
The FDA amended the emergency use authorization for the Novavax COVID-19 vaccine, adjuvanted for use in individuals 12 years and older to include the 2023-2024 formula. The monovalent vaccine authorized for one dose in previously vaccinated individuals and two doses in unvaccinated individuals has been updated to incorporate the spike protein from the omicron variant lineage XBB.1.5 (2023-2024 formula).

Risks Associated with Compounded Ketamine for Treatment of Psychiatric Disorders 10/10/23
The FDA reminded patients and health care providers that ketamine lacks FDA approval for psychiatric disorders and its safety and efficacy remain undetermined. Using compounded ketamine products without provider monitoring for sedation, dissociation, and changes in vital signs poses risks of serious adverse events, including abuse, psychiatric issues, blood pressure elevation, respiratory depression, and lower urinary tract and bladder symptoms.

Concerns About Probiotic Products Used in Hospitalized Preterm Infants 10/26/23
The FDA sent a letter to health care providers advising them of the risk that probiotic products pose to preterm infants in hospital settings. Products are being sold to treat or prevent diseases in this setting, including necrotizing enterocolitis, however, no product is approved for this use and use of probiotic products may have contributed to invasive disease and infant death. Warning letters have been sent to several manufacturers. The FDA acknowledges the conflicting data in the literature and encourages conduct of clinical trials to provide definitive evidence.

FDA Warns Consumers Not to Use Certain Over-the-Counter Eye Drops 10/27/23, 10/30/23
The FDA warned consumers not to use listed over-the-counter eye drops due to the potential risk of eye infections that could result in vision loss or blindness. The FDA has also recommended recall of all lots of these products, and a number of stores, but not all, have removed the products from shelves. Affected products are marketed under the following brands: CVS Health, Equate, Leader (Cardinal Health), Rugby (Cardinal Health), Rite Aid, Target Up & Up, and Velocity Pharma. A current list of affected and recalled products can be found on the FDA site.

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

4.2% Sodium Bicarbonate and 1% and 2% Lidocaine Injections, Hospira: Recall – Glass Particulate 10/02/23
Hospira recalled 4.2% Sodium Bicarbonate Injection, USP 5 mEq/20 mL vial (lot GJ5007), 1% Lidocaine HCl Injection, USP 50 mg/5 mL (Lot 42290DK), and 2% Lidocaine HCl Injection, USP 100 mg/5 mL (lot GH6567) distributed from 11/13/22 through 11/26/22 due to the potential for presence of glass particulate matter.

ION* Sinus Support, ION* Sinus, and Restore Sinus Nasal Sprays: Recall – Contamination 10/02/23
Biomic Sciences recalled to the consumer level all lots of ION* Sinus Support, ION* Sinus, and Restore Sinus nasal sprays after FDA testing found the products to contain microbial contamination with *Microbacterium* sp., *Fictibacillus* sp., *Bacillus* sp., and *Paenibacillus* sp.

Betaxolol Tablets, USP 10 mg, KVK-Tech, Inc.: Recall – Foreign Tablet in Batch 10/03/23
KVK-Tech recalled Lot 17853A (NDC 10702-013-01), expiring June 2027, after a single 5 mg oxycodone HCL tablet was found on the packaging line during batch packaging.

Over-the-Counter Drugs and Medical Devices, Family Dollar: Recall – Improper Storage 10/10/23
Family Dollar recalled OTC drugs and devices that were stored outside temperature requirements, inadvertently shipped to stores, and sold between 6/1/23 and 10/4/23 at stores in AL, AR, AZ, CA, CO, FL, GA, ID, KS, LA, MS, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, and WY. A full list of products can be found on the FDA site.

8.4% Sodium Bicarbonate Injection, Midazolam in 0.8% Sodium Chloride Injection, and Elcys (cysteine hydrochloride Injection), Exela Pharma Sciences, LLC: Recall - Particulate Matter 10/25/23
Exela recalled several lots of three products labeled under the Exela or Civica brands: 8.4% sodium bicarbonate injection 50 mEq/50 mL (Exela lots P0001429, P0001900, P0001902, P0001903, P0001909, P0001945, P0002002, and P0002052, and Civica lot P0001912), Midazolam in 0.8% Sodium Chloride Injection (Exela lot 10001088), and Elcys (cysteine hydrochloride Injection) (Exela lot 10000798). The products were recalled due to the presence of silicone particulate observed in retained samples.

Over-the-Counter Eye Drops 10/30/23
Multiple over-the-counter eye drop recalls were announced starting on 10/30/23 and ongoing. See the FDA site for a current list of the recalls, which includes products labeled by Leader, Major, and Rugby, as well as products pulled from distribution by additional retailers.

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***
Artri King capsules*	Arthritis pain and inflammation	Diclofenac[1]
Kuka Flex Forte capsules*	Arthritis pain and inflammation	Diclofenac[1]
Reumo Flex capsules*	Arthritis pain and inflammation	Diclofenac[1]
The Rock	Sexual enhancement	Sildenafil

*recalled

New Product Shortages	***Date Initially Posted***
Nitroglycerin injectable	10/6/23

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Technetium Tc-99m Sodium Pertechnetate Generator (RadioGenix System, NorthStar Medical Radioisotopes, LLC)	10/17/23
Mesalamine Capsule, Delayed Release (Delzicol, Abbvie Inc.): generics remain available	10/25/23

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Etrasimod / Velsipity / Pfizer	Sphingosine 1-phosphate receptor modulator for the treatment of ulcerative colitis	10/12/23
Bimekizumab-bkzx / Bimzelx / UCB Inc.	Interleukin 17A and F antagonist for the treatment of moderate to severe plaque psoriasis	10/17/23
Zilucoplan / Zilbrysq / UCB Inc.	Complement inhibitor for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive	10/17/23
Mirikizumab-mrkz / Omvoh / Eli Lilly and Co.	Interleukin-23 antagonist for the treatment of moderately to severely active ulcerative colitis in adults	10/26/23
Vamorolone / Agamree / Santhera	Corticosteroid for the treatment of Duchenne muscular dystrophy in patients 2 years and older	10/26/23
Toripalimab-tpzi / Loqtorzi / Coherus Biosciences Inc.	Programmed death receptor-1 blocking antibody for use in the treatment of nasopharyngeal carcinoma	10/27/23

New Indications:	***Description***	***Date Approved***
Patiromer / Veltassa / Vifor Pharma, Inc.	Indication expanded to include treatment of hyperkalemia in pediatric patients 12 years and older	10/2/23
Ranibizumab-Nuna / Byooviz / Samsung Bioepis Co Ltd	Interchangeable with Lucentis (ranibizumab injection) for intravitreal injection for neovascular (wet) age related macular degeneration, macular edema following retinal vein occlusion, and myopic choroidal neovascularization	10/4/23
Encorafenib / Braftovi / Array BioPharma Inc.	In combination with binimetinib, for the treatment of adult patients with metastatic non-small cell lung cancer with a BRAF V600E mutation	10/11/23
Roflumilast / Zoryve / Arcutis Biotherapeutics	Indication expanded to include patients 6 years of age and older with plaque psoriasis	10/12/23
Nivolumab / Opdivo / Bristol-Myers Squibb	For the adjuvant treatment of completely resected Stage IIB, IIC, III, or IV melanoma in patients 12 years and older	10/13/23
Pembrolizumab / Keytruda / Merck Sharp & Dohme LLC	With platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single-agent in post-surgical adjuvant treatment for resectable (tumors ≥4 cm or node positive) non-small cell lung cancer	10/16/23
Etanercept / Enbrel / Immunex	Indication expanded to include treatment of active juvenile psoriatic arthritis in patients 2 years of age and older	10/18/23
Vosoritide / Voxzogo / BioMarin Pharm	Indication expanded to include all pediatric patients to increase linear growth in pediatric patients with achondroplasia with open epiphyses	10/20/23
Ivosidenib / Tibsovo / Servier	For the treatment of adult patients with relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 mutation	10/24/23
Faricimab-svoa / Vabysmo / Genentech, Inc.	Treatment of macular edema following retinal vein occlusion	10/26/23
Abatacept / Orencia / Brist-Myers Squibb Co.	Indication expanded to include treatment of active psoriatic arthritis in patients 2 years and older	10/30/23
Pembrolizumab / Keytruda / Merck Sharp & Dohme LLC	In combination with gemcitabine and cisplatin for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer	10/31/23
Secukinumab / Cosentyx / Novartis	Treatment of adult patients with moderate to severe hidradenitis suppurativa	10/31/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Secukinumab / Cosentyx / Novartis Pharms Corp	Intravenous Infusion: 125 mg/5 mL single dose vial; administered as an intravenous infusion after dilution over a period of 30 minutes for the treatment of adults with psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondylarthritis	10/6/23
Acetaminophen and Ibuprofen / Combogesic IV / AFT Pharmaceuticals	Intravenous Infusion: 1,000 mg/100 mL (10 mg/mL) of acetaminophen and 300 mg/100 mL (3 mg/mL) of ibuprofen in single-dose vial for use in adults where an intravenous route of administration is considered clinically necessary for the relief of mild to moderate pain, and the management of moderate to severe pain as an adjunct to opioid analgesics	10/17/23

New Dosage Forms or Formulation (continued):	***Description***	***Date Approved***
Pilocarpine HCl / Qlosi / Orasis Pharmaceuticals, LTD.	Ophthalmic solution: pilocarpine hydrochloride 0.4% (4 mg/mL) in a single-patient-use vial for the treatment of presbyopia in adults	10/17/23
Tenapanor HCl / Xphozah / Ardelyx Inc.	Tablets: 10, 20, and 30 mg; to reduce serum phosphorus in adults with chronic kidney disease on dialysis as add-on therapy in those with an inadequate response to phosphate binders or who are intolerant to any dose of phosphate binder therapy	10/17/23
Clindamycin Phosphate, Adapalene, And Benzoyl Peroxide / Cabtreo / Bausch Health US, LLC.	Topical gel: clindamycin phosphate 1.2%, adapalene 0.15%, and benzoyl peroxide 3.1%; for the topical treatment of acne vulgaris in adult and pediatric patients 12 years of age and older	10/20/23
Entrectinib / Rozlytrek / Genentech Inc.	Oral pellets: 50 mg per packet for adult patients with ROS1-positive metastatic non-small cell lung cancer and adult/pediatric patients over 1 month old with NTRK gene fusion solid tumors without known acquired resistance mutations, who are either in a metastatic stage or not suitable for surgery and have experienced treatment progression or lack alternative therapy options.	10/20/23
Infliximab / Zymfentra / Celltrion	Injectable: 120 mg/mL in a single-dose prefilled pen for subcutaneous administration in adult patients with moderately to severely active ulcerative colitis or Crohn's disease following prior treatment with intravenous infliximab products, serving as a maintenance option.	10/20/23
Oxaprozin / Coxanto / Solubiomix	Capsules: 300 mg; for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and juvenile rheumatoid arthritis	10/20/23
Ustekinumab-auub / Wezlana / Amgen	Injection: 45 mg/0.5 mL or 90 mg/mL (prefilled syringes) and 45 mg/0.5 mL (single dose vial) for subcutaneous injection, and 130 mg/26 mg/mL (single dose vial) for IV infusion; biosimilar to Stelara for the treatment of plaque psoriasis, active psoriatic arthritis, and active Crohn's disease	10/31/23

Compiled by:

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Etrasimod / Velsipity / Pfizer	
Generic Name / Brand Name / Company	Etrasimod / Velsipity / Pfizer
Date of approval	10/12/23
Drug Class (Mechanism of Action if novel agent)	Sphingosine 1-phosphate receptor modulator; immunomodulator
Indication	Treatment of moderately to severely active ulcerative colitis in adults
Comparative agent – Therapeutic interchange?	Ozanimod
Dosage forms/strengths.	Tablets: 2 mg
Common Dose/sig	2 mg orally once daily
DEA Schedule	NA
Date of market availability	November 2023
Similar Medication Names	Etravirine, Velivet
Clinical Use Evaluation	
Common Adverse Effects	>5%: headache, elevated liver tests, dizziness
Severe Adverse Effects	See warnings
Severe Drug-Drug Interactions	Anti-arrhythmic drugs, QT prolonging drugs, beta-blockers, calcium channel blockers, anti-neoplastic therapies, immune-modulating therapies, moderate to strong inhibitors of CYP2C9 and CYP3A4, moderate to strong inhibitors of CYP2C8 or CYP3A4 in CYP2C9 poor metabolizers, rifampin: see labeling; live vaccines: avoid during and for 5 weeks after treatment
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	CBC, hepatic transaminases, bilirubin
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild to moderate hepatic impairment or in renal impairment. Use in severe hepatic impairment is not recommended.
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Contraindications: • Myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or class III or IV heart failure in the last 6 months • History or presence of Mobitz type II second-degree or third-degree AV block, sick sinus syndrome, or sino-atrial block unless functioning pacemaker Warnings: Infection risk, bradyarrhythmia and atrioventricular conduction delays, liver injury, macular edema, increased blood pressure, fetal risk, malignancies, posterior reversible encephalopathy syndrome, respiratory effects, unintended additive immune system effects from prior immunomodulating therapies. Prior to initiating therapy assess CBC, electrocardiogram, liver function tests, ophthalmic fundus evaluation, current or prior medication, vaccinations, and a skin examination.
Special administration technique or considerations	Swallow tablet whole, with or without food.
Prepared by	Terri Levien
Source	Velsipity (etrasimod) [prescribing information]. New York, NY: Pfizer Labs; October 2023.

Bimekizumab-bkzx / Bimzelx / UCB Inc.	
Generic Name / Brand Name / Company	Bimekizumab-bkzx / Bimzelx / UCB Inc.
Date of approval	10/17/23
Drug Class (Mechanism of Action if novel agent)	Interleukin-17A and F antagonist
Indication	Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
Comparative agent – Therapeutic interchange?	Secukinumab
Dosage forms/strengths.	Injection: 160 mg/mL single-dose prefilled syringe or autoinjector
Common Dose/sig	320 mg (two 160 mg injections) subcutaneously at weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. A dose of 320 mg every 4 weeks after week 16 may be considered for patients weighing 120 kg or more.
DEA Schedule	NA
Date of market availability	November 2023
Similar Medication Names	Mirikizumab
Clinical Use Evaluation	
Common Adverse Effects	≥1%: upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes simplex infections, acne, folliculitis, other candida infections, fatigue
Severe Adverse Effects	Depression and suicidal ideation, inflammatory bowel disease
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.	Liver enzymes, alkaline phosphatase, and bilirubin prior to initiating and periodically
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustments recommended; avoid use in patients with acute liver disease or cirrhosis
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Evaluate patients for tuberculosis infection and complete all age-appropriate vaccinations prior to initiating. Warnings: Monitor for suicidal ideation and behavior; weigh risks and benefits in patients with a history of severe depression. Monitor for infection; do not initiate therapy if active infection is present. Monitor for liver biochemic abnormalities. Avoid use in patients with active inflammatory bowel disease; monitor for new onset or exacerbation
Special administration technique or considerations	Administer subcutaneously in abdomen, thighs, or upper arms; patients may self-inject in abdomen or thigh after training in technique.
Prepared by	Terri Levien
Source	Bimzelx (bimekizumab-bkzx) [prescribing information]. Smyrna, GA: UCB, Inc.; October 2023.

Zilucoplan / Zilbrysq / UCB Inc.	
Generic Name / Brand Name / Company	Zilucoplan / Zilbrysq / UCB Inc.
Date of approval	10/17/23
Drug Class (Mechanism of Action if novel agent)	Complement C5 inhibitor
Indication	Treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive.
Comparative agent – Therapeutic interchange?	Soliris (eculizumab) and Ultomiris (ravulizumab)
Dosage forms/strengths.	Injection: 16.6 mg/0.416 mL, 23 mg/0.574 mL, or 32.4 mg/0.81 mL in single-dose prefilled syringes
Common Dose/sig	Less than 56 kg: 16.6 mg once daily 56 kg to less than 77 kg: 23 mg once daily 77 kg and above: 32.4 mg once daily
DEA Schedule	NA
Date of market availability	Early 2024, through REMS program
Similar Medication Names	Ziluphane, Zilucaroa, Zilusolane, Zilucora, Zilucorin
Clinical Use Evaluation	
Common Adverse Effects	>10%: Injection site reactions, upper respiratory tract infections, and diarrhea
Severe Adverse Effects	Serious meningococcal infections; pancreatitis, pancreatic cysts
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.	Baseline amylase and lipase
Used in Pediatric Areas	Safety and effectiveness in pediatric patients have not been established
Renal or Hepatic Dosing	No dose adjustment is required in patients with renal impairment or mild or moderate hepatic impairment; the pharmacokinetics of zilucoplan have not been studied in patients with severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Contraindicated in patients with unresolved *Neisseria meningitidis* infection. Warnings: Increased risk of meningococcal infections. Vaccinate for meningococcal infections at least 2 weeks before first dose. Use with caution with patients with any other systemic infections. Pancreatitis and pancreatic cysts have been reported; discontinue use in patients with suspected pancreatitis and initiate appropriate management until pancreatitis is ruled out or has resolved.
Special administration technique or considerations	Administer subcutaneously in abdomen, thighs, or upper arms; patients may self-inject in abdomen or thigh after training in technique. Dose should be administered at approximately the same time each day.
Prepared by	Adian Maloney
Source	Zilucoplan (Zilbrysq) [prescribing information]. Smyrna, GA: UCB, Inc.; October 2023.

Mirikizumab-mrkz / Omvoh / Eli Lilly and Co.	
Generic Name / Brand Name / Company	Mirikizumab-mrkz / Omvoh / Eli Lilly and Co.
Date of approval	10/26/23
Drug Class (Mechanism of Action if novel agent)	Interleukin-23 antagonist
Indication	Treatment of moderately to severely active ulcerative colitis in adults
Comparative agent – Therapeutic interchange?	Ustekinumab
Dosage forms/strengths.	Injection: 300 mg/15 mL single-dose vial (IV infusion) and 100 mg/mL single-dose prefilled pen (subcutaneous injection)
Common Dose/sig	Induction dose 300 mg IV at weeks 0, 4, and 8, then maintenance dose of 200 mg (two 100 mg injections) subcutaneously at week 12 and every 4 weeks thereafter
DEA Schedule	NA
Date of market availability	November 2023
Similar Medication Names	Mirtazapine, Mirvetuximab soravtansine, Risankizumab
Clinical Use Evaluation	
Common Adverse Effects	>2%: upper respiratory tract infections and arthralgia during induction and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during maintenance therapy
Severe Adverse Effects	Hypersensitivity reactions, infection, hepatotoxicity
Severe Drug-Drug Interactions	Avoid use of live vaccines
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver enzymes and bilirubin at baseline, for 24 weeks of treatment, and routinely thereafter.
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments recommended; consider alternative therapies in patients with evidence of liver cirrhosis.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: history of serious hypersensitivity to drug or excipients. Warnings: hypersensitivity reactions, infection risk, hepatotoxicity Evaluate patients for tuberculosis infection and complete all age-appropriate vaccinations prior to initiating. Do not initiate therapy if clinically important active infection present.
Special administration technique or considerations	Administer IV dose as an infusion over at least 30 minutes. Administer subcutaneous dose in abdomen, thighs, or upper arms; patients may self-inject in abdomen or thigh after training in technique.
Prepared by	Terri Levien
Source	Omvoh (mirikizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; October 2023.

Vamorolone / Agamree / Santhera	
Generic Name / Brand Name / Company	Vamorolone / Agamree / Santhera
Date of approval	10/26/23
Drug Class (Mechanism of Action if novel agent)	Corticosteroid
Indication	Treatment of Duchenne muscular dystrophy in patients 2 years and older
Comparative agent – Therapeutic interchange?	Deflazacort, Prednisone
Dosage forms/strengths.	Oral suspension: 40 mg/mL
Common Dose/sig	6 mg/kg orally once daily up to a maximum daily dose of 300 mg for patients weighing more than 50 kg
DEA Schedule	NA
Date of market availability	First quarter 2024
Similar Medication Names	Nandrolone, Oxandrolone
Clinical Use Evaluation	
Common Adverse Effects	>10%: cushingoid features, psychiatric disorders, vomiting, weight increased, vitamin D deficiency
Severe Adverse Effects	Endocrine function alterations, immunosuppression, gastrointestinal perforation
Severe Drug-Drug Interactions	Strong CYP3A4 inhibitors: reduced vamorolone dose recommended
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Sodium, potassium
Used in Pediatric Areas	Indicated for use in patients 2 years and older; safety and efficacy not established in pediatric patients younger than 2 years
Renal or Hepatic Dosing	In mild to moderate hepatic impairment, the recommended dose is 2 mg/kg orally once daily up to a maximum daily dosage of 100 mg for patients weighing more than 50 kg; there is no experience in severe hepatic impairment. No dosage adjustments recommended in renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity to drug or excipients Warnings: monitor for alterations in endocrine function, immunosuppression and increased infection risk, increased blood pressure, gastrointestinal perforation, behavioral and mood disorders, decreased bone mineral density. Administer age-appropriate immunizations prior to initiating therapy; give live-attenuated or live vaccines at least 4 to 6 weeks before starting therapy.
Special administration technique or considerations	Administer with food. Shake suspension well for about 30 seconds before administration. Use only provided oral syringe; dispense dose directly into the mouth. Decrease dose gradually when used for more than one week.
Prepared by	Terri Levien
Source	Agamree (vamorolone) [prescribing information]. Burlington, MA: Santhera Pharmaceuticals (USA), Inc.; October 2023.

Toripalimab-tpzi / Loqtorzi / Coherus Biosciences Inc.	
Generic Name / Brand Name / Company	Toripalimab-tpzi / Loqtorzi / Coherus Biosciences Inc.
Date of approval	10/27/23
Drug Class (Mechanism of Action if novel agent)	Programmed death receptor-1 (PD-1)-blocking antibody
Indication	For first-line treatment of metastatic or recurrent locally advanced nasopharyngeal carcinoma when used with cisplatin and gemcitabine, or for use as a single agent for the treatment of recurrent unresectable or metastatic nasopharyngeal carcinoma with disease progression on or after a platinum-containing chemotherapy
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Injection: 240 mg/6 mL single-dose vial
Common Dose/sig	In combination with cisplatin and gemcitabine: 240 mg IV every 3 weeks As a single agent: 3 mg/kg IV every 2 weeks
DEA Schedule	NA
Date of market availability	First quarter 2024
Similar Medication Names	None identified
Clinical Use Evaluation	
Common Adverse Effects	In combination: (≥20%) nausea, vomiting, decreased appetite, constipation, hypothyroidism, rash, pyrexia, diarrhea, peripheral neuropathy, cough, musculoskeletal pain, upper respiratory infection, insomnia, dizziness, malaise Single agent: (≥20%) fatigue, hypothyroidism, musculoskeletal pain
Severe Adverse Effects	Immune-mediated adverse reactions (pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, dermatologic reactions, solid organ transplant rejection), infusion 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.	Liver enzymes, creatinine, thyroid function at baseline and periodically thereafter
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments are recommended; has not been studied in moderate or severe hepatic or renal impairment. Withhold or discontinue in patients developing immune-mediated nephritis with renal dysfunction.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Warnings: immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic hematopoietic stem cell transplant, embryofetal toxicity; withhold therapy for severe immune-mediated reactions and permanently discontinue for life-threatening reactions, recurrent reactions, or inability to reduced prednisone dose.
Special administration technique or considerations	Infuse first infusion over 60 minutes; subsequent infusions can be administered over 30 minutes if no reaction occurred during the first infusion. When administered on the same day as chemotherapy, toripalimab-tpzi should be administered prior to chemotherapy.
Prepared by	Terri Levien
Source	Loqtorzi (toripalimab-tpzi) [prescribing information]. Redwood City, CA: Coherus BioSciences, Inc.; October 2023.