WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 9/1/22 – 9/30/22

FDA Drug Safety Communications & Drug Information Updates:

Mother's Touch Formula: FDA MedWatch Alert 9/7/22
The FDA issued an alert to consumers, pharmacies, and health professionals that Mother's Touch Formula is being marketed as an infant formula without FDA authorization and that the formula is not manufactured in compliance with FDA infant formula regulations. Parents and caregivers are advised not to buy or give this formula.

Medtronic MiniMed 600 Series Insulin Pump System – Potential Cybersecurity Risk 9/20/22
There is a potential issue associated with the communication protocol for the pump system that could allow unauthorized access to the pump system. The FDA is working with Medtronic to identify and prevent adverse events associated to this vulnerability and will provide additional information as it becomes available.

FDA Issues Immediately-In-Effect Guidance Regarding Distribution of Approved Naloxone Products 9/22/22
The FDA updated the guidance document clarifying the scope of the public health emergency exclusion and exemption under the Drug Supply Chain Security Act (DSCSA) as they apply to the distribution of FDA-approved naloxone products. This update emphasizes the importance of access and availability for underserved communities through harm reduction programs and related entities. The document can be found on the FDA website.

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

Clearlink Basic Solution Set with Duovent by Baxter: Recall – Risk of Leaks 9/15/22
Baxter Healthcare Corporation recalled Clearlink Basic Solution Set with Duovent after customer reports of leaks. The Clearlink Basic Solution Sets with Duovent are primarily used for the delivery of chemotherapy drugs; leakage could expose healthcare professionals and patients to these hazardous substances.

Antica Ocean Citron Hand Sanitizer (Alcohol) Gel 65%, Salon Technologies: Recall – Contains Benzene 9/20/22
Salon Technologies International, Inc. recalled one lot of Antica Ocean Citron Hand Sanitizer (alcohol) gel 65% (lot 1166A, expiration 6/18/2023) to the consumer level due to the presence of benzene.

Acyclovir Sodium Injection 500 mg per 10 mL (50 mg/mL), Eugia US: Recall – Particulate Matter 9/29/22
Eugia US LLC (formerly AuroMedics Pharma LLC) recalled lot number AC22006 of AuroMedics Acyclovir Sodium Injection 500 mg per 10 mL (50 mg/mL), 10 mL single dose vial (NDC 55150-154-10) due to a product complaint for the presence of a dark red, brown, and black particulate inside the vial. Products were distributed between 6/8/22 and 6/13/22.

Atenolol 25 mg and Clopidogrel 75 mg Tablets, Golden State Medical Supply: Recall – Label Mix-up 9/30/22
Golden State Medical Supply recalled clopidogrel 75 mg tablets (lot# GS046745, 1000 count bottle) that was mislabeled as atenolol 25 mg tablets; both tablets are being recalled out of an abundance of caution (NDC 51407-032-10 and NDC 60429-027-10).

LifeSPARC System Controller, LivaNova (TandemLife): Recall - Risk of Extended Pump Stop 9/30/22
LivaNova (TandemLife) recalled the LifeSPARC Controller due to a software malfunction that may trigger the device to enter Critical Failure mode—clearing the controller screen and issuing an alarm that cannot be muted or turned off. If the user does not follow specific instructions in the Operations Manual and powers off the frozen controller prior to setting up the backup controller, the pump may stop for an extended period of time during the replacement process.

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***
Wonder Pill Capsules*	Sexual Enhancement	Tadalafil

*recalled

New Product Shortages	***Date Initially Posted***
Oxytocin Injection	9/23/22

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Oxaliplatin (Eloxatin and Winthrop Oxaliplatin, Sanofi-Aventis); remains available as generic	9/8/22
Spironolactone and hydrochlorothiazide 50 mg/50 mg (Aldactazide, Pfizer); 25 mg strength remains available as brand and generics	9/8/22
Hyoscyamine sulfate injection (Levsin, Meda Pharmaceuticals); remains available from other manufacturers	9/13/22
Efavirenz capsules (Sustiva, Bristol-Myers Squibb Co.); generics and tablets remain available	9/28/22

New Drug Approvals:	***Description (*See Attached Drug Summaries)***	***Date Approved***
Spesolimab-sbzo / Spevigo / Boehringer Ingelheim Pharmaceuticals Inc.	Interleukin-36 receptor antagonist for the treatment of generalized pustular psoriasis flares in adults*	9/1/22
Daxibotulinumtoxina-lanm / Daxxify / Rvance Therapeutics Inc.	Botulinum toxin preparation indicated for intramuscular injection for temporary improvement of moderate to severe glabellar lines	9/7/22
Deucravacitinib / Sotyktu / Bristol Myers Squibb Co.	Tyrosine kinase 2 inhibitor for the treatment of moderate-to-severe plaque psoriasis*	9/8/22
Terlipressin / Terlivaz / Mallinckrodt Hospital Products Inc.	Vasopressin receptor agonist indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function*	9/14/22
Elivaldogene autotemcel / Skysona / bluebird bio, Inc.	Gene therapy to slow the progression of neurologic dysfunction in boys with early, active cerebral adrenoleukodystrophy	9/16/22
Omidenepag isopropyl / Omlonti / Santen Inc.	Selective prostaglandin E2 receptor agonist indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension*	9/22/22
Sodium phenylbutyrate and taurursodiol / Relyvrio / Amylyx Pharmaceuticals, Inc.	Oral suspension for the treatment of amyotrophic lateral sclerosis (ALS) in adults*	9/29/22
Futibatinib / Lytgobi / Taiho Oncology, Inc.	Kinase inhibitor for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements*	9/30/22

New Indications:	***Description***	***Date Approved***
Durvalumab / Imfinzi / AstraZeneca Pharmaceuticals LP	In combination with gemcitabine and cisplatin for the treatment of adult patients with locally advanced or metastatic biliary tract cancer	9/2/22
Selpercatinib / Retevmo / Loxo Oncology, Inc.	For use in adults with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options	9/21/22
Selpercatinib / Retevmo / Loxo Oncology, Inc.	For use in adults with locally advanced or metastatic non-small cell lung cancer with a RET gene fusion	9/21/22
Risankizumab-rzaa / Skyrizi / AbbVie, Inc.	For the treatment of moderately to severely active Crohn's disease in adults	9/23/22
Dupilumab / Dupixent / Regeneron Pharmaceuticals, Inc.	For the treatment of adults with prurigo nodularis	9/29/22
Amifampridine / Firdapase / Catalyst Pharmaceuticals, Inc.	Indication expanded for the treatment of pediatric patients with Lambert-Eaton myasthenic syndrome age 6 to less than 17 years	9/30/22

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Aprepitant / Aponvie / Heron Therapeutics, Inc.	Intravenous emulsion: 32 mg/4.4 mL in a single dose vial; for the prevention of postoperative nausea and vomiting in adults	9/16/22
Sodium thiosulfate / Pedmark / Fennec Pharmaceuticals, Inc.	Injection: 12.5 g/100 mL single-dose vial; to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors (see attached drug summary)	9/20/22
Chloroprocaine / Iheezo / Sintetica SA	Ophthalmic gel 3%; for ocular surface anesthesia	9/27/22

Compiled by:

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Spesolimab-sbzo / Spevigo / Boehringer Ingelheim Pharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Spesolimab-sbzo / Spevigo / Boehringer Ingelheim Pharmaceuticals, Inc.
Date of approval	9/1/22
Drug Class (Mechanism of Action if novel agent)	Interleukin-36 receptor antagonist; reduces downstream activation of pro-inflammatory and pro-fibrotic pathways
Indication	Treatment of generalized pustular psoriasis flares in adults
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Injection: 450 mg/7.5 mL in single-dose vial
Common Dose/sig	Administer single 900 mg dose by intravenous infusion; may repeat one week after initial dose if flare symptoms persist
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	None identified
Clinical Use Evaluation	
Common Adverse Effects	≥5%: asthenia, fatigue, nausea, vomiting, headache, pruritus, prurigo, infusion site hematoma, bruising, urinary tract infection
Severe Adverse Effects	Hypersensitivity, infection, Guillain-Barre syndrome
Severe Drug-Drug Interactions	Do not administer live vaccines concurrently with spesolimab
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None; assess for active tuberculosis prior to initiation
Used in Pediatric Areas	Safety and efficacy in pediatric patients have not been established
Renal or Hepatic Dosing	No dosage adjustments specified for renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: severe or life-threatening hypersensitivity to spesolimab or any product excipients Warnings: Infection risk may be increased Evaluate for tuberculosis before initiating treatment Hypersensitivity and infusion-related reactions may occur
Special administration technique or considerations	Administer by intravenous infusion over 90 minutes through an IV line containing a 0.2 micron in-line filter. Total infusion time should not exceed 180 minutes. A pre-existing IV line may be used, but should be flushed with 0.9% sodium chloride injection prior to and after the infusion.
Prepared by	Terri Levien
Source	Spevigo (spesolimab-sbzo) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; September 2022.

Deucravacitinib / Sotyktu / Bristol-Myers Squibb	
Generic Name / Brand Name / Company	Deucravacitinib / Sotyktu / Bristol-Myers Squibb
Date of approval	9/8/22
Drug Class (Mechanism of Action if novel agent)	Tyrosine kinase 2 (TYK2) inhibitor; TYK2 is a member of the Janus kinase (JAK) family
Indication	Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy; not for use in combination with other potent immunosuppressants
Comparative agent – Therapeutic interchange?	Janus kinase inhibitors (tofacitinib, baricitinib, ruxolitinib)
Dosage forms/strengths.	Tablets: 6 mg
Common Dose/sig	6 mg orally once daily, with or without food
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Deutetrabenazine, Sotylize
Clinical Use Evaluation	
Common Adverse Effects	≥1%: upper respiratory infection, blood creatinine phosphokinase increased, herpes simplex, mouth ulcers, folliculitis, acne
Severe Adverse Effects	Hypersensitivity, malignancies, rhabdomyolysis, infection
Severe Drug-Drug Interactions	Avoid use with live vaccines
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Evaluate serum triglycerides periodically. Evaluate liver enzymes at baseline and thereafter in patients with known or suspected liver disease. Evaluate for tuberculosis before initiating treatment
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment needed for patients with renal impairment or mild to moderate hepatic impairment Use is not recommended in patients with severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: history of hypersensitivity to deucravacitinib or any of the product excipients Warnings: Hypersensitivity reactions such as angioedema have been reported. Infection risk may be increased. Evaluate for tuberculosis before initiating treatment. Malignancies, including lymphoma, were observed in clinical trials. Rhabdomyolysis and elevated CPK has been observed. It is not known whether deucravacitinib may be associated with the adverse reactions observed with JAK inhibitors.
Special administration technique or considerations	Do not crush, cut, or chew tablets.
Prepared by	Terri Levien
Source	Sotyktu (deucravacitinib) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022.

Terlipressin / Terlivaz / Mallinckrodt Hospital Products Inc.	
Generic Name / Brand Name / Company	Terlipressin / Terlivaz / Mallinckrodt Hospital Products Inc.
Date of approval	9/13/22
Drug Class (Mechanism of Action if novel agent)	Vasopressin receptor agonist
Indication	To improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function; patients with serum creatinine greater than 5 mg/dL are unlikely to benefit
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Injection: 0.85 mg of terlipressin as a lyophilized powder in single-dose vials
Common Dose/sig	Days 1 – 3: administer 0.85 mg IV every 6 hours Day 4: If SCr has decreased by ≥ 30% from baseline, continue 0.85 mg IV every 6 hours. If SCr has deceased < 30% from baseline, dose may be increased to 1.7 mg IV every 6 hours.
DEA Schedule	None
Date of market availability	October 2022
Similar Medication Names	Trileptal, vasopressin
Clinical Use Evaluation	
Common Adverse Effects	≥10%: Abdominal pain, nausea, respiratory failure, diarrhea, dyspnea
Severe Adverse Effects	Respiratory failure, ischemic events
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.	Monitor oxygen saturation with pulse oximetry. Obtain serum creatinine at baseline; adjust dose on day 4 based on changes in serum creatinine. Assess Acute-on-Chronic Liver Failure (ACLF) grade and volume status before initiating treatment.
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	Patients with serum creatinine >5 mg/dL are unlikely to experience benefit. No dose adjustments required in hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications Patients experiencing hypoxia or worsening respiratory symptoms Patients with ongoing coronary, peripheral, or mesenteric ischemia Warnings/precautions Serious or fatal respiratory failure Adverse reactions may make patient ineligible for liver transplant May cause cardiac, cerebrovascular, peripheral, or mesenteric ischemic events Embryo-fetal toxicity
Special administration technique or considerations	Administer through a peripheral or central line (dedicated central line not required). Flush the line after administration.
Prepared by	Darren Miguel
Source	Terlivaz (terlipressin) [prescribing information]. Bedminster, NJ: Mallinckrodt Hospital Products Inc.; September 2022.

Omidenepag isopropyl / Omlonti / Sanden Inc.	
Generic Name / Brand Name / Company	Omidenepag isopropyl / Omlonti / Sanden Inc.
Date of approval	9/22/22
Drug Class (Mechanism of Action if novel agent)	Selective prostaglandin E2 receptor agonist
Indication	Reduction of intraocular pressure in patients with open-angle glaucoma
Comparative agent – Therapeutic interchange?	Bimatoprost, latanoprost, travoprost
Dosage forms/strengths.	Ophthalmic solution 0.002% (0.02 mg/mL)
Common Dose/sig	One drop in the affected eye(s) once daily in the evening
DEA Schedule	None
Date of market availability	Not announced
Similar Medication Names	Olumiant
Clinical Use Evaluation	
Common Adverse Effects	≥1%: Conjunctival hyperemia, photophobia, blurred vision, dry eye, instillation site pain, eye pain, ocular hyperemia, punctate keratitis, headache, eye irritation, visual impairment
Severe Adverse Effects	Ocular inflammation, macular edema
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	Not applicable
Important Labs Values to assess prior to order entry or at point of clinical follow up.	No required lab monitoring; monitor intraocular pressure to assess response
Used in Pediatric Areas	Safety and efficacy have not been 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/precautions Permanent pigmentation of irises Eyelash changes Ocular inflammation Macular edema Risk of contamination and potential injury to the eye
Special administration technique or considerations	Advise patients to avoid touching the tip of the bottle to the eye or any surface. Shake bottle gently prior to administration. If more than 1 topical ophthalmic drug administered, separate by at least 5 minutes. Remove contact lenses prior to administration; may reinsert 15 minutes after administration.
Prepared by	Brittney Kessel
Source	Omlonti (omidenepag isopropyl) [prescribing information]. Emeryville, CA: Santen Inc.; September 2022.

Sodium phenylbutyrate and taurursodiol / Relyvrio / Amylyx Pharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Sodium phenylbutyrate and taurursodiol / Relyvrio / Amylyx Pharmaceuticals, Inc.
Date of approval	9/29/22
Drug Class (Mechanism of Action if novel agent)	Histone deacetylase inhibitor and bile acid; mechanism unknown
Indication	Treatment of amyotrophic lateral sclerosis (ALS) in adults
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Powder for oral suspension (sodium phenylbutyrate 3 g / taurursodiol 1 g)
Common Dose/sig	1 packet taken orally or via feeding tube once daily for 3 weeks and twice daily thereafter
DEA Schedule	None
Date of market availability	Late October 2022
Similar Medication Names	Sodium phenylbutyrate, ursodiol
Clinical Use Evaluation	
Common Adverse Effects	≥15%: diarrhea, abdominal pain, nausea, upper respiratory tract infections
Severe Adverse Effects	None
Severe Drug-Drug Interactions	Bile acid sequestrants, probenecid, and aluminum-based antacids
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Sodium levels or water retention in those sensitive to salt intake
Used in Pediatric Areas	Safety/efficacy has not been established
Renal or Hepatic Dosing	No dose adjustments in mild renal or hepatic impairment. Avoid in moderate to severe renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings Disorders that interfere with bile acid circulation, pancreatic disorders, intestinal disorders Patients sensitive to high salt intake
Special administration technique or considerations	Powder is to be mixed with 8 oz of room temperature water and administered within 1 hour of preparation. Administer before a snack or meal.
Prepared by	Brittney Kessel
Source	Relyvrio (sodium phenylbutyrate/taurursodiol) [prescribing information]. Cambrige, MA; Amylyx Pharmaceuticals, Inc: September 2022

Futibatinib / Lytgobi / Taiho Oncology, Inc.	
Generic Name / Brand Name / Company	Futibatinib / Lytgobi / Taiho Oncology, Inc.
Date of approval	9/30/22
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor
Indication	For the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements
Comparative agent – Therapeutic interchange?	Erdafitinib, infigratinib, and pemigatinib
Dosage forms/strengths.	4 mg tablets
Common Dose/sig	20 mg orally once daily
DEA Schedule	None
Date of market availability	2022
Similar Medication Names	None
Clinical Use Evaluation	
Common Adverse Effects	>20%: nail toxicity, musculoskeletal pain, constipation, diarrhea, fatigue, dry mouth, alopecia, stomatitis, abdominal pain, dry skin, arthralgia, dysgeusia, dry eye, nausea, decreased appetite, urinary tract infection, palmar-plantar erythrodysesthesia syndrome, vomiting Lab abnormalities > 20%: increased phosphate, increased creatinine, decreased hemoglobin, increased glucose, increased calcium, decreased sodium, decreased phosphate, increased ALT, increased alkaline phosphatase, decreased lymphocytes, increased AST, decreased platelets, increased aPTT, decreased leukocytes, decreased albumin, decreased neutrophils, increased creatine kinase, increased bilirubin, decreased glucose, increased prothrombin INR, decreased potassium
Severe Adverse Effects	Retinal Pigment Epithelial Detachment (RPED), hyperphosphatemia, palmar-plantar erythrodysesthesia syndrome, diarrhea, stomatitis, abdominal pain, nausea, vomiting, fatigue, decreased appetite, musculoskeletal pain, dry eye, urinary tract infection, weight decreased
Severe Drug-Drug Interactions	Dual P-gp and strong CYP3A inhibitors and inducers
Severe Drug-Food Interactions	Avoid grapefruit
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Phosphate, CBC, LFTs; verify pregnancy status of females of reproductive potential prior to initiating
Used in Pediatric Areas	Safety and efficacy have not been established
Renal or Hepatic Dosing	No dosage adjustment specified; not assessed in severe renal impairment or moderate to severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: None Warnings Ocular toxicity Hyperphosphatemia and soft tissue mineralization Embryo-fetal toxicity
Special administration technique or considerations	Do not crush, chew, split or dissolve tablets. Administer with or without food at approximately the same time each day. If dose missed by 12 or more hours or vomiting occurs after a dose, resume administration with the next scheduled dose.
Prepared by	Brittney Kessel
Source	Lytgobi (futibatinib) [prescribing information]. Princeton, NJ; Taiho Oncology, Inc: September 2022

Sodium thiosulfate / Pedmark / Fennec Pharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Sodium thiosulfate / Pedmark / Fennec Pharmaceuticals, Inc.
Date of approval	9/20/22
Drug Class (Mechanism of Action if novel agent)	Antidote
Indication	To reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month and older with localized, non-metastatic solid tumors
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Injection: 12.5 g/100 mL in single dose vial
Common Dose/sig	Body weight < 5 kg: 10 g/m2 Body weight 5 to 10 kg: 15 g/m2 Body weight > 10 kg: 20 g/m2 Administer as IV infusion over 15 minutes starting 6 hours after completion of cisplatin infusion; if multiday cisplatin regimen, administered 6 hours after each infusion but at least 10 hours before the next cisplatin infusion
DEA Schedule	None
Date of market availability	Fourth quarter 2022
Similar Medication Names	Sodium thiosulfate (other formulations)
Common Adverse Effects	>25% (with difference between arms of >5% compared to cisplatin alone): vomiting, nausea, decreased hemoglobin, hypernatremia, hypokalemia
Severe Adverse Effects	Hypersensitivity reactions, nausea, vomiting, hypernatremia, hypokalemia, hypophosphatemia, hypermagnesemia, stomatitis
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.	Serum sodium and potassium at baseline and as clinically indicated
Used in Pediatric Areas	Pediatric patients 1 month and older; safety and efficacy not established in patients younger than 1 month or in pediatric patients with metastatic cancer. Not recommended in patients younger than 1 month due to increased risk of hypernatremia.
Renal or Hepatic Dosing	No recommended adjustments
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: history of severe hypersensitivity to sodium thiosulfate or any product ingredients (may contain sodium sulfite) Warnings: Monitor for hypersensitivity reactions, hypernatremia and hypokalemia Nausea and vomiting; administer antiemetics prior to each dose Follow recommended dosage modifications for hypersensitivity, hypernatremia, hypokalemia, and other adverse reactions.
Special administration technique or considerations	Administer as IV infusion over 15 minutes 6 hours after completion of cisplatin infusion. Administered antiemetics before each sodium thiosulfate infusion. If patient experiences hypersensitivity reaction, administer antihistamines and glucocorticoids before each subsequent infusion.
Prepared by	Terri Levien
Source	Pedmark (sodium thiosulfate) [prescribing information]. Hoboken, NJ: Fennec Pharmaceuticals, Inc.; September 2022.