Highlights of FDA Activities – 11/1/25 – 11/30/25

FDA Drug Safety Communications & Drug Information Updates:

Menopausal Hormone Therapies – Labeling Changes 11/10/25

The FDA authorized labeling changes for menopausal hormone therapies. The following changes were authorized for the boxed warning for systemic and local vaginal products: removal of language related to cardiovascular disease, breast cancer, and probable dementia, removal of language related to endometrial cancer except in the systemic estrogen-alone drugs, and removal of the recommendation to use the lowest effective dose for the shortest amount of time. The FDA also authorized removal of the probable dementia warning from the Warnings section. In the labeling for the systemic products, the FDA authorized addition of consideration of starting hormone therapy for moderate to severe vasomotor symptoms of menopause in women less than 60 years old or less than 10 years since menopause, addition of WHI data in women 50 to 59 years of age, retention of the boxed warning about endometrial cancer in the systemic estrogen-alone products, and retention of information about cardiovascular disease and breast cancer warnings. In the labeling for the vaginal estrogen products, the FDA authorized condensing the safety information and prioritizing information most relevant to the local vaginal formulation.

Elevidys (delandistrogene moxeparvovec-rokl) – New Safety Warning 11/14/25

The FDA announced labeling changes for Elevidys including addition of a boxed warning and changes to the indication following reports of fatal acute liver failure in non-ambulatory patients treated with the product. The specific changes include the boxed warning describing the risk of serious liver injury and acute liver failure, limiting the indication to ambulatory patients with Duchenne muscular dystrophy (DMD) who are 4 years of age and older with a confirmed mutation of the DMD gene, removal of the indication for non-ambulatory patients with DMD, addition of a Limitation of Use statement to guide clinical decision-making, updates to the Warnings and Precautions, Dosage and Administration, Adverse Reactions, Use in Specific Populations, Clinical Studies, and Patients Counseling Information sections, and inclusion of a new Medication Guide. Specific monitoring recommendations include weekly liver function tests for at least 3 months after treatment and weekly testing for cardiac injury (troponin-I) for one month after treatment.

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

Potassium Chloride Injection 20 mEq, Otsuka ICU Medical: Recall – Mislabeled as 10 mEq 11/3/25

Otsuka ICU Medical LLC recalled one lot (1030613, expiration date 09-30-2026) of potassium chloride injection 20 mEq (NDC 0990-7077-14) as the overwrap label may incorrectly identify it as potassium chloride injection 10 mEq. The correct labeling on the product bag is not visible when the incorrectly labeled overwrap is in place.

Famotidine Injection USP 20 mg, Fresenius Kabi: Recall – Out of Specification Endotoxin Results 11/7/25

Fresenius Kabi recalled 3 lots of famotidine injection USP 20 mg/2 mL vials (product code 730912; lots 6133156, 6133194, 6133388) due to out-of-specification endotoxin results in reserved samples.

ByHeart Whole Nutrition Infant Formula: Recall – Infant Botulism 11/8, 11/11, 11/14, 11/19, 11/20, 11/26

The FDA and CDC are investigating an outbreak of infant botulism. Affected infants had consumed ByHeart infant formula. As of 11/26/25, 37 cases have been reported in 17 states. The recalled infant formula was distributed online and nationwide at major retailers. On 11/8, two lots of ByHeart Whole Nutrition Infant Formula (206VABP/251261P2 and 206VABP/251131P2, both with use by date of 01 Dec 2026) were initially recalled. On 11/12, the recall was expanded to all batches of ByHeart Whole Nutrition Infant Formula in cans (UPC: 85004496800, 24 oz cans) or in Anywhere Packs (UPC: 85004496802, 0.6 oz packets). No ByHeart infant formula should continue to be sold. Parents and caregivers should be instructed to stop use of any ByHeart infant formula

immediately. If a child who consumed the formula is experiencing symptoms, immediately medical attention should be sought. Physicians suspecting a case of infant botulism should immediately call 510-231-7600 for case consultation. If a child consumed the formula but is not showing symptoms, parents/caregivers should continue to monitor the child, take a photo or record the information on the bottom of the package, keep the product in a safe spot and label it DO NOT USE. If the child develops symptoms, the container should be provided to the health department for testing. If the child does not develop symptoms after 30 days, the container should be discarded. Updated information can be found on the FDA site.

Ivenix Large Volume Pump Primary Administration Sets, Fresenius Kabi: Recall – Reverse Flow Issue 11/24/25
Fresenius Kabi issued an early alert to affected customers advising that certain Ivenix large volume pump (LVP) primary administration sets be removed from areas where they are used or sold due to a defect within a specific lot where the drip chamber and Luer Lock are in reversed positions. This defect can result in reverse flow, as well as delay in fluid delivery. The affected product is LVP Primary Administration Set, Dual-Inlet, Low-Sorbing, Needle-Free Port, Dual Y-Site (product code SET-0032-01 [individual set] and SET-0032-25 [case], lot FA25B03126, unique device identifier 00811505030214).

Alaris Pump, Becton Dickinson: Correction Alert – Damaged Units 11/28/25
Becton Dickinson issued a correction alert advising that Alaris Pump Modules that have been dropped or severely jarred may have damage to internal components that may not be apparent or readily visible, but could cause under infusion, over infusion, unregulated flow, or failure of the module to calibrate. Instructions for the use of these devices have been updated. Devices that have been dropped or severely jarred should be removed from use and thoroughly tested and inspected prior to reuse.

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***
All Members Mark Super Greens*	Vitamins/minerals	Salmonella
mR.7 SUPER 700000	Sexual enhancement	Sildenafil, tadalafil
Organic Moringa Leaf Powder (1 kilogram box, africaimports.com)*	Immunity	Salmonella
Organic Moringa Leaf Powder (Food to Live brand)*	Immunity	Salmonella
Organic SUPER GREENS powder mix (Food to Live brand)*	Vitamins/minerals	Salmonella
SdB ELITE	Tejocote supplement	Yellow oleander
SdB Semilla de Brasil Tejocote Root	Tejocote supplement	Yellow oleander
SiluetaYa Mexican Tejocote Roots*	Tejocote supplement	Yellow oleander

*recalled

New Product Shortages (per FDA or ASHP)	***Date Initially Posted***
Chlorothiazide oral suspension	11/4/25
Iodine and potassium iodide (Lugol's solution or strong iodine oral solution)	11/10/25
Leucovorin calcium tablets	11/11/25
Insulin human regular premixed solution for injection	11/25/26
Dipyridamole injection	11/26/25

ASHP Drug Shortages List contains up to-date information on drug shortages

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Lasmiditan succinate 50 mg and 100 mg tablets (Reyvow, Eli Lilly and Co); patients will need to be switched to an alternative treatment for acute migraine	11/3/25
Atazanavir sulfate and cobicistat tablet (Evotaz, Bristol Myers Squibb Co0; production ceases April 2026	11/3/25
Acetaminophen and oxycodone hydrochloride tablets (Percocet, Endo Pharmaceuticals)	11/3/25
Deferiprone tablet (Ferriprox, Chiesi USA); generics remain available	11/7/25
Ceftazidime injection (Tazicef, Pfizer); generics remain available	11/14/25
Montelukast chewable tablet 4 mg (Singulair, Organon); generics remain available	11/17/25
Hydrochlorothiazide capsule (Microzide, Teva); generics remain available	11/19/25

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Doxecitine and doxribtimine/Kygevvi/ UCB Inc	Pyrimidine nucleosides for the treatment of thymidine kinase 2 deficiency in adults and pediatric patients with an age of symptom onset on or before 12 years	11/3/25
Ziftomenib/Komzifti/Kura Oncology	Menin inhibitor for the treatment of adult patients with relapsed/refractory acute myeloid leukemia with susceptible NPM1 mutation who have no satisfactory alternative treatment options	11/13/25
Plozasiran/Redemplo/Arrowhead Pharmaceuticals	Apolipoprotein C-III-directed small interfering ribonucleic acid for use as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome	11/18/25
Sevabertinib/Hyrnuo/Bayer HealthCare Pharmaceuticals	A kinase inhibitor for the treatment of adults with locally advanced or metastatic, non-squamous non-small cell lung cancer whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations and who have received prior systemic therapy	11/19/25
Sibeprenlimab-szsi/Voyxact/Otsuka America Pharmaceutical	An A Proliferation Inducing Ligand (APRIL) blocker to reduce proteinuria in primary immunoglobulin A nephropathy in adults at risk for disease progression	11/25/25

New Indications:	***Description***	***Date Approved***
Linaclotide/Linzess/AbbVie	Treatment of irritable bowel syndrome with constipation in pediatric patients 7 years of age and older	11/4/25
Lumateperone/Caplyta/AbbVie	Adjunctive therapy to antidepressants for the treatment of major depressive disorder in adults	11/5/25
Hyaluronic acid with lidocaine/ Restylane Lyft/Galderma	Augmentation of the chin region to improve the chin profile I patients over 21 years of age with mild-to-moderate chin retrusion	11/5/25
Daratumumab and hyaluronidase-fihj/Darzaelex Faspro/Janssen Biotech	Treatment of patients with high-risk smoldering multiple myeloma	11/6/25
Epcoritamab-bysp/Epkinly/AbbVie	In combination with lenalidomide and rituximab for relapsed or refractory follicular lymphoma	11/18/25
Antithrombin III/Thrombate/Grifols	Indication expanded to include treatment of hereditary antithrombin deficiency to include pediatric patients	11/18/25
Aflibercept/Eylea HD/Novo Nordisk	Treatment of macular edema after a retinal vein occlusion	11/19/25
Selumetinib/Koselugo/AstraZeneca	Indication expanded to include treatment of adults with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas	11/19/25

New Indications continued:	***Description***	***Date Approved***
Enfortumab vedotin-ejfv/Padcev/ Astellas	In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph as neoadjuvant treatment followed by adjuvant treatment after cystectomy for patients with muscle-invasive bladder cancer who are ineligible for cisplatin	11/21/25
Pembrolizuamb and berahyaluronidase alfa-pmph/Keytruda QLEX/Merck	In combination with enfortumab vedotin-efjv as neoadjuvant treatment followed by adjuvant treatment after cystectomy for patients with muscle-invasive bladder cancer who are ineligible for cisplatin	11/21/25
Pembrolizuamb/Keytruda/Merck	In combination with enfortumab vedotin-efjv as neoadjuvant treatment followed by adjuvant treatment after cystectomy for patients with muscle-invasive bladder cancer who are ineligible for cisplatin	11/21/25
Atezolizumab and hyaluronidase-tqjs/Tecentriq Hybreza/Genentech	Indication expanded to include use in the treatment of unresectable or metastatic alveolar soft part sarcoma in pediatric patients 12 years and older who weigh at least 40 kg	11/24/25
Nivolumab and hyaluronidase-nvhy/ Opdivo Qvantig/Bristol-Myers Squibb	Indication expanded to include treatment of melanoma and unresectable or metastatic microsatellite instability-high or mismatch repair deficient colorectal cancer in pediatric patients 12 years and older	11/24/25
Durvalumab/Imfinzi/AstraZeneca	In combination with FLOT (fluorouracil, leucovorin, oxaliplatin, and docetaxel) as neoadjuvant and adjuvant treatment, followed by single agent durvalumab, for adult patients with resectable gastric and gastroesophageal junction adenocarcinoma	11/25/25

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Onasemnogene abeparvovec-brve/ Itvisma/Novartis	Suspension for intrathecal administration; gene therapy for treatment of adults and pediatric patients 2 years and older with spinal muscular atrophy and confirmed mutation in the survival motor neuron 1 (SMN1) gene	11/24/25
Ranitidine/VKT Pharma	Tablets: 150 mg and 300 mg; reformulated ranitidine tablets must be stored in the original container and protected from moisture, with the desiccant in the bottle, and unused tablets must be discarded after 90 days of opening the bottle or by the expiration date on the bottle, whichever is sooner	11/24/25

Compiled by:

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Doxecitine and doxribtimine/Kygevvi/UCB Inc	
Generic Name/Brand Name/Company	Doxecitine and doxribtimine/Kygevvi/UCB Inc
Date of approval	11/3/25
Drug Class (Mechanism of Action if novel agent)	Pyrimidine nucleoside supplementation for incorporation into skeletal muscle mitochondrial DNA; in animal models this restored mitochondrial DNA copy number.
Indication	Treatment of thymidine kinase 2 deficiency in adults and pediatric patients with an age of symptom onset on or before 12 years
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Powder for oral solution: doxecitine 2 g and doxribtimine 2 g
Common Dose/sig	Initial dose: 260 mg/kg/day (doxecitine 130 mg and doxribtimine 130 mg) administered orally in 3 equally divided doses with food; titrate to intermediate dose after a minimum of 2 weeks (520 mg/kg/day consisting of doxecitine 260 mg and doxribtimine 260 mg) and then to the maintenance dose after a minimum of 2 weeks at the intermediate dose (800 mg/kg/day consisting of doxecitine 400 mg and doxribtimine 400 mg)
DEA Schedule	N/A
Date of market availability	1st quarter 2026
Similar Medication Names	Doxycycline
Clinical Use Evaluation	
Common Adverse Effects	Diarrhea (72%), abdominal pain (23%), vomiting (21%), ALT increased (21%), AST increased (17%)
Severe Adverse Effects	Diarrhea, vomiting, liver injury
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.	Transaminase (ALT and AST) and total bilirubin levels prior to treatment initiation; monitor annually or as clinically indicated
Used in Pediatric Areas	Indicated for use in patients 12 years and older with no dosage adjustment; safety and efficacy not established in younger patients
Renal or Hepatic Dosing	No specific dosing adjustments in renal impairment although plasma concentrations were increased in moderate or severe renal impairment. Pharmacokinetics have not been studied in hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: no labeled contraindications Warnings: Interrupt therapy if signs or symptoms of liver injury are observed; may consider restarting at last tolerated dose, but consider permanently discontinuing if signs/symptoms persist or worsen Reduce dose or interrupt treatment if severe diarrhea or vomiting occurs; consider discontinuing permanently if persistent or recurring symptoms; monitor for dehydration and treat promptly with electrolyte replacement
Special administration technique or considerations	Administer dosage orally in 3 equally divided doses approximately 6 hours apart (plus or minus 2 hours) with food. Depending on patient weight, 1 to 16 packets may be required to prepare the daily dose. Followed labeled instructions for volume of water to be used for reconstitution. Use the provided administration kit to prepare and administer the prescribed dose. May administer via feeding tube.
Prepared by	Terri Levien
Source	Kygevvi (doxecitine and doxribtimine) [prescribing information]. Smyrna, GA: UCB, Inc; November 2025.

Ziftomenib/Komzifti/Kura Oncology	
Generic Name/Brand Name/Company	Ziftomenib/Komzifti/Kura Oncology
Date of approval	11/13/25
Drug Class (Mechanism of Action if novel agent)	Menin inhibitor
Indication	Treatment of adult patients with relapsed/refractory acute myeloid leukemia with susceptible nucleophosmin 1 (NPM1) mutation who have no satisfactory alternative treatment options
Comparative agent – Therapeutic interchange?	Venetoclax-based regimens
Dosage forms/strengths	Capsules: 200 mg
Common Dose/sig	600 mg orally once daily
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Zituvimet
Clinical Use Evaluation	
Common Adverse Effects	>20%: infection, hemorrhage, diarrhea, nausea, fatigue, edema, pruritus, musculoskeletal pain, differentiation syndrome, febrile neutropenia, increased transaminases
Severe Adverse Effects	Differentiation syndrome, QTc interval prolongation, infection, hemorrhage, hypertension, diarrhea, fatigue, febrile neutropenia, increased transaminases, renal impairment, hypoxia
Severe Drug-Drug Interactions	Avoid concomitant use with strong or moderate CYP3A4 inducers, proton pump inhibitors, H2 receptor antagonists or antacids (see administration below), or drugs that prolong QTc interval. Monitor frequently if used with strong or moderate CYP3A inhibitors.
Severe Drug-Food Interactions	Grapefruit: avoid; food increases absorption; take on empty stomach
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Select patients based on presence of an NPM1 mutation; monitor electrolytes prior to initiation and during therapy; do not initiate until WBC count is reduced to less than 25 x 10^9/L; verify pregnancy status in females of reproductive potential prior to initiating
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild or moderate renal or hepatic impairment; the effects of severe renal or hepatic impairment have not been studied
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: Differentiation syndrome (boxed warning): can be fatal; monitor for signs/symptoms including fever, joint pain, hypotension, hypoxia, dyspnea, rapid weight gain or peripheral edema, pleural or pericardial effusion, pulmonary infiltrates, acute kidney injury, rash QTc interval prolongation: monitor electrocardiograms and electrolytes, correct hypokalemia and hypomagnesemia prior to treatment; interrupt therapy if QTc interval is greater than 500 ms. Embryo-fetal toxicity: can cause fetal harm
Special administration technique or considerations	Administer on an empty stomach at least 1 hour before or 2 hours after a meal. Administer at the same time each day. Swallow capsules whole. If concomitant use with H2 receptor antagonist is necessary, take ziftomenib 2 hours before or 10 hours after. If concomitant use with an antacid is necessary, take ziftomenib 2 hours before or 2 hours after.
Prepared by	Terri Levien
Source	Komzifti (ziftomenib) [prescribing information]. San Diego, CA: Kura Oncology Inc; November 2025.

Plozasiran/Redemplo/Arrowhead Pharmaceuticals	
Generic Name/Brand Name/Company	Plozasiran/Redemplo/Arrowhead Pharmaceuticals
Date of approval	11/18/25
Drug Class (Mechanism of Action if novel agent)	Apolipoprotein C-III (apoC-III)-directed small interfering ribonucleic acid; reduction of apoC-III protein leads to increased clearance of serum triglycerides
Indication	Adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome
Comparative agent – Therapeutic interchange?	Olezarsen
Dosage forms/strengths	Injection: 25 mg/0.5 mL in single-dose prefilled syringe
Common Dose/sig	25 mg subcutaneously once every 3 months
DEA Schedule	N/A
Date of market availability	Before the end of 2025
Similar Medication Names	Plazomicin
Clinical Use Evaluation	
Common Adverse Effects	Hyperglycemia, headache, nausea, injection site reaction
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known; patients should adhere to a low-fat diet
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Disease state monitoring (triglycerides, LDL-C)
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 renal impairment or mild hepatic impairment. The effect of severe renal impairment or moderate to severe hepatic impairment on plozasiran are not known.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: none in labeling
Special administration technique or considerations	Inject into the front of the thigh or abdomen; upper outer arm may be used as injection site if administered by healthcare provider or caregiver.
Prepared by	Terri Levien
Source	Redemplo (plozasiran) [prescribing information]. Pasadena, CA: Arrowhead Pharmaceuticals Inc; November 2025.

Sevabertinib/Hyrnuo/Bayer HealthCare Pharmaceuticals	
Generic Name/Brand Name/Company	Sevabertinib/Hyrnuo/Bayer HealthCare Pharmaceuticals
Date of approval	11/19/25
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor
Indication	Treatment of adults with locally advanced or metastatic, non-squamous non-small cell lung cancer whose tumors have HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutations and who have received prior systemic therapy
Comparative agent – Therapeutic interchange?	Zongertinib
Dosage forms/strengths	Tablets: 10 mg
Common Dose/sig	20 mg orally twice daily with food
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Hyrimoz, sevelamer
Clinical Use Evaluation	
Common Adverse Effects	>20%: diarrhea, rash, paronychia, stomatitis, nausea
Severe Adverse Effects	>2%: decreased potassium, increased lipase, decreased lymphocytes, decreased sodium, increased amylase, increased ALT, increased AST
Severe Drug-Drug Interactions	Strong CYP3A inhibitors: avoid or reduce sevabertinib dose Moderate CYP3A inhibitors: monitor for adverse reactions Strong and moderate CYP3A inducers: avoid concomitant use Certain CYP3A substrates: avoid use with substrates where minimal increases in concentration may lead to serious adverse reactions Certain P-gp substrates: refer to prescribing information for P-gp substrates where increases in concentration may lead to adverse reactions
Severe Drug-Food Interactions	Grapefruit or grapefruit juice: avoid
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Select patients for treatment based on presence of HER2 (ERBB2) TKD activating mutations; monitor liver function tests (ALT, AST, total bilirubin) at baseline, every 2 weeks during the first month, and then monthly; monitor amylase and lipase regularly; verify pregnancy status in females of reproductive potential prior to initiating
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustments in mild to moderate renal impairment or mild hepatic impairment; the effects of severe renal impairment or moderate to severe hepatic impairment on sevabertinib are not known
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: Diarrhea Hepatotoxicity: monitor liver function tests Interstitial lung disease/pneumonitis: discontinue therapy if confirmed Ocular toxicity: refer patients with new or worsening eye symptoms Pancreatic enzyme elevation: monitor amylase and lipase Embro-fetal toxicity: can cause fetal harm
Special administration technique or considerations	Administer with food. Swallow tablets whole.
Prepared by	Terri Levien
Source	Hyrnuo (sevabertinib) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; November 2025.

Sibeprenlimab-szsi/Voyxact/Otsuka America Pharmaceutical	
Generic Name/Brand Name/Company	Sibeprenlimab-szsi/Voyxact/Otsuka America Pharmaceutical
Date of approval	11/25/25
Drug Class (Mechanism of Action if novel agent)	A Proliferation Inducing Ligand (APRIL) blocker; inhibition of APRIL results in reduced levels of serum galactose-deficient immunoglobulin A1, which has been implicated in the pathogenesis of immunoglobulin A nephropathy
Indication	To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk for disease progression
Comparative agent – Therapeutic interchange?	Other immunosuppressive therapies (eg, systemic corticosteroids, targeted-release budesonide, mycophenolate mofetil, iptacopan)
Dosage forms/strengths	Injection: 400 mg/2 mL in single-dose prefilled syringe
Common Dose/sig	400 mg subcutaneously once every 4 weeks
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Voxzogo, Voydeya
Clinical Use Evaluation	
Common Adverse Effects	Upper respiratory tract infection (15%), injection site erythema (13%)
Severe Adverse Effects	None reported
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 prior to medication administration; disease state monitoring includes serum creatinine and urine protein
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	No dosing adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity Cautions: Immunosuppression and infection risk: monitor for signs and symptoms of infection; if serious infection occurs, consider interrupting therapy. Avoid use of live vaccines within 30 days prior to initiation of sibeprenlimab-szsi therapy or during treatment.
Special administration technique or considerations	Allow prefilled syringe to come to room temperature for 15 to 30 minutes before injecting. Inject into the front of the thigh or abdomen; may be administered to back of upper arm if caregiver is administering.
Prepared by	Terri Levien
Source	Voyxact (sibeprenlimab-szsi) [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical Inc; November 2025.