Highlights of FDA Activities – 7/1/26 – 7/31/26

FDA Drug Safety Communications & Drug Information Updates:

Product	Description	Date of Update
General Anesthesia: Drug Information Update – Neurologic Complications Linked to Genetic Variant in Patients of Maternal Venezuelan Ancestry	The FDA is investigating the safety of sevoflurane and other general anesthetics following published reports of severe neurologic adverse outcomes and death in adults and pediatric patients of maternal Venezuelan ancestry following routine general anesthesia with sevoflurane. A rare mitochondrial genetic variant (MT-ND4 m. 11232T>C) has been reported in a subset of patients who experienced serious adverse reactions with sevoflurane, although the genetic variant raises concerns with all volatile anesthetics. Considering the recent earthquakes in Venezuela, the FDA advises agencies and groups providing medical resources to Venezuelans and health care providers in Venezuela may consider using alternatives to volatile anesthetics, such as intravenous anesthetics or regional anesthesia, where clinically appropriate and available.	7/6/26

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

Product	Description	Date Announced
Ivenix Large Volume Infusion Pumps, Fresenius Kabi: Corrections – Software	Fresenius Kabi issued a recall that involves a software correction for Ivenix Large Volume Infusion Pumps. Letters were sent to affected users. Software version 5.10.2 embedded in the LVP-0004 has been recalled due to an anomaly that affects use while on battery power. Until the software update is available in July 2026, the pump should remain plugged in at all times.	7/7/26
Ivenix Large Volume Infusion Pumps, Fresenius Kabi: Corrections – Dropped or Jarred Units	Fresenius Kabi corrected instructions for Ivenix Large Volume Infusion Pumps that have been dropped or severely jarred. Units that have been dropped or severely jarred should be removed from use immediately, even if no damage is visible. The touchscreens on such units have been observed to display unintended behaviors including random screen touches and lack of screen responsiveness.	7/7/26

Product	Description	Date Announced
Medline Convenience Kits Containing Recalled ChloraPrep Clear and FREPP Clear Applicators, BD: Correction – Remove Component Recalled due to Fungal Contamination	Medline issued a letter to affected customers recommending certain convenience kits have recalled BD ChloraPrep applicators removed prior to use. BD recalled lot 4032183 of ChloraPrep Clear 1 mL Single Sterile and lot 4073005 of FREPP Clear 1.5 mL applicators with paper lidding due to fungal contamination allowing growth of *Aspergillus penicillioides*. The full list of recalled convenience kits can be found on the FDA site. Labels should be applied to all affected kits stating that the affected applicators must be removed and discarded prior to use of the kit. The other kit components may still be sued.	7/9/26
Spinal Anesthesia Kits containing Huons Bupivacaine HCl in Dextrose Injection, USP, B. Braun Medical: Recall – Infection Risk and Reduced Effectiveness	B. Braun Medical Inc is advising removal of certain spinal anesthesia kits, including B. Braun PENCAN Spinal Needle Procedure Kits, B. Braun Spinocan Spinal Needle Procedure Kits, and B. Braun Spinocan Spinal Tray Spinal Needle Anesthesia Procedure Kits, from use due to inclusion of a recalled Huons Bupivacaine Hydrochloride in Dextrose Injection USP within the kits. The bupivacaine product was recalled due to increased infection risk and/or reduced effectiveness of the product. A complete list of recalled kits can be found on the FDA site. Recalled kits should be quarantined immediately.	7/16/26
Arrow Kits and Sets Convenience Kits containing Huons Lidocaine and Bupivacaine and Saline: Correction – Remove Recalled Components	Arrow International advised customers to correct certain convenience kits, including Arrow Kits and Sets containing 0.9% sodium chloride (10 mL ampule) and lidocaine and Arrow Kits and Sets containing lidocaine and bupivacaine due to inclusion of recalled Huons components in the kits. Users are instructed to discard the saline, lidocaine, and bupivacaine ampules upon opening the kit. A complete list of affected products can be found on the FDA site.	7/16/26
Cetirizine Hydrochloride Tablets USP 5 mg, Unique Pharmaceuticals Laboratories: Recall – Potential Cross Contamination	Four lots of Unique Pharmaceuticals Laboratories cetirizine hydrochloride 5 mg tablets have been recalled due to potential cross contamination with another drug, ranitidine. Lot numbers with NDC 16571-401-10 being recalled: GY825029, GY825030, GY825031, and GY825032 (all exp. 10/2028).	7/18/26
Duo-Vent Solution Set and Male Luer Lock Adapter, Baxter: Remove from Use – Air Bubbles in Drip Chamber	Baxter issued an alert advising customers to remove from use Duo-Vent Solution Set and Male Luer Lock Adapter (product code 1C8507, Lots DR2627062, DR26D14031, DR26E13055) due to possible air bubbles in the drip chamber or tubing	7/20/26

Product	Description	Date Announced
	when a pressure cuff is in use or when the tubing is flushed at the fully open position. Affected lot numbers should be immediately located, isolated, and removed from use.	
Cefazolin in Dextrose Injection USP, 2 g/100 mL, Baxter: Recall – Particulate Matter	Baxter International Inc recalled one lot (LD175708, Exp 14-Feb 2027) of cefazolin in dextrose injection 2 g/100 mL single-dose infusion bags due to particulate matter in the solution identified as cardboard. The recalled product was distributed from 3/25/25 to 6/30/25.	7/24/26
Cyclophosphamide for Injection, USP, 1 g and 2 g vials, Sunny Pharmtech Inc: Recall – Particulate Matter	Sunny Pharmatech Inc recalled three lots of cyclophosphamide for injection, USP, 1 g/50 mL and 2 g/100 mL vials due to the presence of particulate matter identified as steel. Recalled product was distributed from May 2024 to October 2024. The recalled lots (C23019V1, C24015V1, C24010V1) remain within expiry until October 2026, April 2027, and March 2027, respectively.	7/24/26
Papaverine Hydrochloride Injection, USP 60 mg/2 mL, American Regent Inc: Recall – Particulate Matter	American Regent Inc recalled one lot (#25202, expiration date 11/30/26) of papaverine HCl injection, USP, 60 mg/2 mL single dose vials due to the presence of visible particulate matter identified as glass and/or paraformaldehyde. Product was distributed nationwide beginning 9/30/25.	7/27/26
Convenience Kits from Argon Medical Containing Spectra Medical Device Lidocaine Ampules: Correction – Remove Recalled Component	Argon Medical is recommending certain convenience kits used during surgical procedures be corrected due to the presence of Spectra Medical Device lidocaine ampules affected by the Huons Co, Ltd recall. Argon has issued a letter to affected customers and the list of affected products can be found on the FDA site. Overlabels should be placed on the affected product instructing staff to remove and discard the lidocaine ampules. The remaining kit components may be used.	7/30/26

Dietary Supplement/Natural Product 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
Detoxi Slim	Weight loss	Sibutramine[1]
Kangaroo Intense Venus 3000	Sexual enhancement	Sildenafil
MAGNUM brand products	Sexual enhancement	Sildenafil, tadalafil
Xian Ling	Pain	Meloxicam, tapentadol
Zen Principle Moringa capsules by Relay Peak Research*[,2]	Immune support	*Salmonella*

**recalled*

[1]Sibutramine has been associated with increased cardiovascular events; it is a controlled substance that was removed from the market for safety reasons in 2010[FDA]

New Product Shortages (per FDA or ASHP)

Product	Date Posted
Tocilizumab-aazg injection	7/1/26
Calcitriol injection	7/7/26
Adalimumab-ryvk injection	7/10/26
Iodixanol injection	7/16/26
Methohexital injection	7/17/26
Rifampin injection	7/26/26
Pegfilgrastim-bmez injection	7/28/26

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

Brand Name or Sole Source Product Discontinuations/Withdrawals

Product	Date Posted
Aspirin suppository (Padagis US)	7/23/26
Belladonna and opium suppository (Padagis US)	7/23/26
Bendamustine hydrochloride injection solution (Treanda, Cephalon); powder for injection remains available	7/23/26
Hydrocortisone acetate suppository (Padagis US)	7/23/26
Hydromorphone hydrochloride suppository (Padagis US)	7/23/26
Morphine sulfate suppository (Pagagis US)	7/23/26
Podophyllum resin topical tincture (Podocon 25, Padagis US LLC)	7/23/26

Product	Date Posted
Lopinavir and ritonavir oral solution (Kaletra, AbbVie); generic tablets remain available	7/24/26
Lopinavir and ritonavir tablet (Kaletra, AbbVie); generics remain available	7/24/26
Ritonavir oral powder (Norvir, AbbVie); alternative ritonavir formulations remain available	7/24/26
Ritonavir tablet (Norvir, AbbVie); generics remain available	7/24/26
Fluticasone propionate and salmeterol xinafoate aerosol, metered (Advair HFA, GSK); the 120 dose presentation will remain available	7/27/26

New Drug Approvals

Product	Description (See Attached Drug Summaries)	Date Approved
Atacicept-vymj/Trutakna/Vera Therapeutics	B-lymphocyte stimulator-specific inhibitor and A Proliferation Inducing Ligand (APRIL) blocker to reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk for disease progression	7/7/26
Gedatolisib/Revtorpyk/Celcuity	Multitarget kinase inhibitor for use in combination with fulvestrant, with or without palbociclib, for adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer without a PIK3CA mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting	7/14/26
Enlicitide/Lipfendra/Merck	Oral PCSK9 inhibitor for use with diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH)	7/16/26
Zidesamtinib/Jideytro/Nuvalent	Kinase inhibitor for the treatment of adults with locally advanced or metastatic ROS1-positive non-small cell lung cancer who received a prior ROS1 kinase inhibitor	7/22/26
Centanafadine/Simtriyo/Otsuka Pharmaceutical	Norepinephrine, dopamine, serotonin reuptake inhibitor (NDSRI) for the treatment of attention-deficit/hyperactivity disorder (ADHD) in patients 6 years and older	7/27/26

New Indications

Product	Description	Date Approved
Exagamglogene autotemcel/Casgevy/ Vertex Pharmaceuticals	Treatment of patients 2 years and older with either sickle cell disease with recurrent vaso-occlusive crises or transfusion-dependent β thalassemia	7/1/26
Von Willebrand Factor/Coagulation Factor VIII Complex (Human)/ Wilate/Octapharma USA	Routine prophylaxis to reduce the frequency of bleeding episodes in Von Willebrand Disease in patients less than 6 years of age	7/2/26
Mometasone furoate and olopatadine hydrochloride/Ryaltris/Glenmark	Treatment of symptoms of seasonal allergic rhinitis in pediatric patients 6 to 12 years of age	7/7/26
Enfortumab vedotin-ejfv/Padcev/ Astellas	In combination with pembrolizumab or pembrolizumab and berahyaluronidase-alfa-pmph as neoadjuvant treatment, and then continued as adjuvant treatment following cystectomy in adults with muscle-invasive bladder cancer	7/10/26
Pembrolizumab/Keytruda/Merck	In combination with enfortumab vedotin-ejfv as neoadjuvant treatment followed by adjuvant treatment following cystectomy in adults with muscle-invasive bladder cancer	7/10/26
Pembrolizumab and berahyaluronidase alfa-pmph/ Keytruda Qlex/Merck	In combination with enfortumab vedotin-ejfv as neoadjuvant treatment followed by adjuvant treatment following cystectomy in adults with muscle-invasive bladder cancer	7/10/26
Rezafungin acetate/Rezzayo/Melinta Therapeutics	Indication expanded to include pediatric patients 12 years and older for treatment of candidemia and invasive candidiasis who have limited or no alternative options.	7/16/26
Lutetium Lu 177 vipivotide tetraxetan/Pluvicto/Novartis	With an androgen receptor pathway inhibitor for the treatment of patients with prostate-specific membrane antigen (PSMA)-positive metastatic androgen pathway modulation-naïve/sensitive prostate cancer (metastatic hormone-sensitive prostate cancer)	7/31/26

New Dosage Forms or Formulation

Product	Description	Date Approved
Isatuximab-irfc/Sarclisa Escena/ Sanofi Aventis US	Injection: 1,400 mg/10 mL single dose vial for administration subcutaneously via the CirCLIQ On-Body delivery system or with a syringe and infusion set for manual administration; indications are the same as for the IV formulation, but the dosage and administration differs	7/9/26
Sodium bicarbonate/Sodium bicarbonate/Amneal EU, Ltd.	Intravenous injection: 150 mEq/1,000 mL (0.15 mEq/mL); new strength indicated for adults and pediatric patients to treat metabolic acidosis and to raise urine pH in drug poisoning in which drug elimination is increased when alkaline	7/9/26
Indocyanine green/Zyogreen/ Provepharm	Injection: 25 mg/10 mL as a ready to use solution in a single dose ampule; for fluorescence imaging of vessels, blood flow, and tissue perfusion before, during, and after vascular, gastrointestinal, organ transplant, plastic, micro- and reconstructive surgeries in adults and pediatric patients; for fluorescence imaging of extrahepatic biliary ducts in adults and pediatric patients from birth to less than 1 year of age and 6 years and older; for fluorescence imaging of lymph nodes and lymphatic vessels during lymphatic mapping in adults with cervical and uterine cancer; and for ophthalmic angiography in adults and pediatric patients	7/10/26
Acetaminophen and naproxen sodium/Tylenol with Naproxen/ Kenvue	Tablet: acetaminophen 325 mg and naproxen sodium 110 mg; for over-the-counter pain relief	7/24/26
Bevacizumab-vikg/Lytenava/Outlook Therapeutics	Injection: 1.25 mg (0.05 mL of 25 mg/mL) in a single-dose glass vial; for the treatment of neovascular age-related macular degeneration	7/24/26
Furosemide/Furoscix ReadyFlow/ MannKind	Injection: 80 mg/mL in single dose prefilled autoinjector; for subcutaneous administration in the abdomen only for the treatment of edema in adults with heart failure or chronic kidney disease	7/23/26
Ezplaz Freeze Dried Plasma/Vascular Solutions LLC	Kit: one unit of freeze-dried plasma sealed in an outer foil pouch, one 250 mL bag of sterile water for injection, one sterile fluid transfer set, and one sterile blood transfusion set; for transfusion in adult patients who need plasma and for whom other plasma products are not available	7/29/26
Norelgestromin and ethinyl estradiol/Gwyn Lo/Viatris	Transdermal system: norelgestromin 220 mcg/day and ethinyl estradiol 20 mcg/day; hormonal contraceptive applied weekly for prevention of pregnancy in women with BMI less than 30 kg/m2	7/29/26

Product	Description	Date Approved
Clonidine/Qlonilik/CMP Development	Oral solution: 0.05 mg/mL; for the treatment of hypertension in adults	7/29/26
Sodium glycerophosphate/ Glycophos/Fresenius Kabi	Injection: 1 mmol/mL; as a source of phosphorus in adults and pediatric patients 12 years and older as part of parenteral nutrition	7/29/26

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New Drug Approvals: Drug Summaries

Atacicept-vymj/Trutakna/Vera Therapeutics

Date of approval	7/7/26
Drug Class/Mechanism of Action	B-lymphocyte stimulator (Blys)-specific inhibitor (B-cell activating factor [BAFF] inhibitor) and A Proliferation Inducing Ligand (APRIL) blocker that reduces BAFF- and APRIL-mediated signaling decreasing production of galactose-deficient IgA1
Indication	Reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk for disease progression
Comparative agent	Budesonide (Tarpeyo, corticosteroid), sparsentan (Filspari, dual endothelin angiotensin receptor antagonist), atrasentan (Vanrafia, neodthelin A receptor blocker), sibeprenlimab (Voyxact, APRIL blocker)
Dosage forms/strengths	Injection: 150 mg/mL single-dose pre-filled autoinjector
Common Dose/sig	150 mg subcutaneously once weekly
DEA Schedule	NA
Date of market availability	August 2026
Similar Medication Names	Abatacept, abacavir, Trulance

Clinical Use Evaluation

Common Adverse Effects	Infections (32%) [upper respiratory tract (12%)], local administration reactions (30%) [injection site reactions (19%), erythema (6%)]
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Systemic corticosteroids – may increase infection risk
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Proteinuria
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity Warnings: Immunosuppression and infection risks - monitor Immunosuppression and immunization risks – avoid live vaccines
Special administration technique or considerations	Allow autoinjector to sit for 15 to 30 minutes at room temperature before use. Injection subcutaneously in abdomen or thigh; rotation injection sites.
Source	Trutakna (atacicept-vymj) [prescribing information]. Brisbane, CA: Vera Therapeutics, Inc; July 2026.

Gedatolisib/Revtorpyk/Celcuity

Date of approval	7/14/26
Drug Class/Mechanism of Action	Multitarget kinase inhibitor of class I PI3K isoforms (α, β, γ,δ), mTORC1 and mTORC2, and effectors including AKT
Indication	In combination with fulvestrant, with or without palbociclib, for adults with HR-positive, HER2-negative locally advanced or metastatic breast cancer without a PIK3CA mutation detected following progression on or after at least one line of endocrine therapy in the metastatic setting
Comparative agent	Alpelisib similar but for use with PIK3CA-mutation
Dosage forms/strengths	Injection: 180 mg as lyophilized powder in single-dose vial
Common Dose/sig	180 mg IV once weekly on days 1, 8, and 15 of a 28-day cycle
DEA Schedule	N/A
Date of market availability	Late 3rd quarter 2026, expanded access program available prior
Similar Medication Names	None identified

Clinical Use Evaluation

Common Adverse Effects (≥20%)	With fulvestrant and palbociclib: stomatitis, nausea, fatigue, vomiting, rash, constipation, diarrhea, musculoskeletal pain; decreased white blood cells, neutrophils, hemoglobin, lymphocytes, platelets, sodium; increased fasting glucose, ALT, AST, eosinophils With fulvestrant: stomatitis, nausea, rash, fatigue, musculoskeletal pain, vomiting, pruritus, and diarrhea; decreased hemoglobin, lymphocytes; increased fasting glucose, eosinophils, ALT, AST
Severe Adverse Effects	Stomatitis, diarrhea, rash, musculoskeletal pain, thrombosis,
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Blood glucose and hemoglobin A1c prior to starting and at regular intervals during treatment
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No specific dosage adjustments for renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in prescribing information Warnings: Stomatitis – initiate steroid-containing mouthwash prophylaxis Dermatologic reactions – monitor, limit sun exposure Hyperglycemia – monitor blood glucose and hemoglobin A1c Embryofetal toxicity
Special administration technique or considerations	Administer IV as a 30-minute infusion in dedicated line with 0.2 or 0.22-micron filter. Flush line with D5W before and after infusion. Do not administer with any chloride-containing solutions (eg, NS, Ringer's Injection, Lactated Ringer's Injection) or other medications.
Source	Revtorpyk (gedatolisib) [prescribing information]. Minneapolis, MN: Celcuity Inc; July 2026.

Enlicitide/Lipfendra/Merck

Date of approval	7/16/26
Drug Class/Mechanism of Action	Oral proprotein convertase subtilisin/Kexin type 9 (PCSK9) inhibitor
Indication	Adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia, including HeFH
Comparative agent	Injectable PCSK9 inhibitors:
Dosage forms/strengths	Film-coated tablet: 20 mg
Common Dose/sig	20 mg orally once daily
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	None identified

Clinical Use Evaluation

Common Adverse Effects	Diarrhea (7%) and dizziness (9%); frequencies of adverse reactions were similar to placebo
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	Administration after a meal reduces and delays absorption
Important Lab Monitoring	LDL-C
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments for renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in prescribing information Warnings: none in prescribing information
Special administration technique or considerations	Take on an empty stomach in the morning with water, black coffee, or plain tea. Swallow tablet whole. Can be taken with other medications. Wait at least 30 minutes before eating food or drinking other beverages.
Source	Enlicitide (Lipfendra) [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; July 2026.

Zidesamtinib / Jideytro / Nuvalent

Date of approval	7/22/26
Drug Class/Mechanism of Action	Tyrosine kinase ROS1 inhibitor
Indication	Treatment of adults with locally advanced or metastatic ROS1-positive non-small cell lung cancer who received a prior ROS1 kinase inhibitor
Comparative agent	Taletrectinib – indicated in ROS1-positive NSCLC
Dosage forms/strengths	Tablets: 25 mg and 100 mg
Common Dose/sig	100 mg orally once daily
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	None identified

Clinical Use Evaluation

Common Adverse Effects	Edema (38%), peripheral neuropathy (25%), constipation (17%), fatigue (16%), dyspnea (15%), increased CPK (37%), increased cholesterol or triglycerides (47%), decreased hemoglobin (30%)
Severe Adverse Effects	Pneumonia, dyspnea, edema, peripheral neuropathy, increased triglycerides, CPK increased, lipase increased, hemoglobin decreased
Severe Drug-Drug Interactions	Avoid use with strong or moderate CYP3A inhibitors or inducers
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Creatine phosphokinase, electrolytes, amylase, lipase
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment for eGFR 30 to 90 mL/min or in mild to moderate hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in prescribing information Warnings: CNS adverse reactions QTc interval prolongation – monitor ECG and electrolytes Interstitial lung disease/pneumonitis Skeletal fractures Myalgia with creatinine phosphokinase elevation – monitor CPK Pancreatic toxicity – monitor lipase and amylase Embryo-fetal harm
Special administration technique or considerations	Taken with or without food. Swallow tablets whole. Withhold and/or reduce dose for adverse reactions (see labeling for specific guidance).
Source	Jideytro (zidesamtinib) [prescribing information]. Cambridge, MA: Nuvalent Inc; July 2026.

Centanafadine / Simtriyo / Otsuka Pharmaceutical

Date of approval	7/27/26
Drug Class/Mechanism of Action	NDSRI; CNS stimulant
Indication	Treatment of ADHD in patients 6 years and older and weighing at least 20 kg
Comparative agent	SNRIs (viloxazine, atomoxetine)
Dosage forms/strengths	Extended-release capsule: 140 mg, 210 mg, 280 mg
Common Dose/sig	6 to 12 years and 20 kg to <35 kg: 140 mg orally once daily 6 to 12 years and 35 to 50 kg: 210 mg orally once daily 6 to 12 years and >50 kg: 280 mg orally once daily 13 to 17 years: 280 mg orally once daily Adults: starting dose 210 mg orally once daily, may increase to 280 mg
DEA Schedule	Pending
Date of market availability	Pending controlled-substance review
Similar Medication Names	None identified

Clinical Use Evaluation

Common Adverse Effects	Patients 6 to 12 years: rash (9%), decreased appetite (8%); 13 to 17 years: decreased appetite (15%), nausea (10%), rash (8%), headache (7%), abdominal pain (5%); adults: headache (5-8%), decreased appetite (5-7%), insomnia (5-7%), nausea (2-7%), dry mouth (3-6%), diarrhea (2-5%)
Severe Adverse Effects	Anaphylaxis, angioedema, suicide attempt, suicidal ideation
Severe Drug-Drug Interactions	Monoamine oxidase inhibitors – contraindicated within 14 days Avoid alcohol consumption at same time or within 2 hours of dosing CYP1A2 substrates – monitor for adverse reactions/reduce dose CNS stimulants – monitor for cardiovascular adverse reactions Serotonergic drugs – serotonin syndrome
Severe Drug-Food Interactions	Alcohol – see above
Important Lab Monitoring	None
Used in Pediatric Areas	Avoid use in patients younger than 6 years or weighing less than 20 kg
Renal or Hepatic Dosing	No adjustments in mild to moderate hepatic impairment or in renal impairment; not recommended in severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity, within 14 days of taking a MAOI, or in patients with pheochromocytoma or a history of pheochromocytoma Boxed warning: suicidal ideation and behaviors, misuse and addiction Warnings: Risk to patients with serious cardiac disease Increased blood pressure and heart rate – monitor Psychiatric adverse reactions Hypersensitivity reactions (including anaphylaxis and angioedema) Long-term suppression of growth in pediatric patients – monitor Peripheral vasculopathy including Raynaud's phenomenon – monitor Serotonin syndrome

	Motor and verbal tics and worsening of Tourette's syndrome – monitor Allergy to FD&C yellow No. 5 dye (tartrazine) in 210 mg capsule Before initiating assess for risk of abuse, misuse or addiction; presence of cardiac disease; heart rate and blood pressure; risk for developing a manic episode; and motor or verbal tics or Tourette's or family history of tics or Tourette's syndrome.
Special administration technique or considerations	Administer in the morning with or without food, at approximately the same time each day. Capsules may be swallowed whole or opened and contents sprinkled on 1 tablespoon (15 mL) applesauce or yogurt, or in 1 tablespoon (15 mL) orange juice. Consume immediately followed by water. Do not chew the granules.
Source	Simtriyo (centanafadine) [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical Inc; July 2026.