WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 6/1/23 – 6/30/23

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

Dronabinol Capsules USP 2.5 mg and Ziprasidone HCl Capsules 20 mg, Harvard Drug Group: Recall – Label Mix-Up 6/14/23

Harvard Drug Group recalled a single lot of dronabinol capsules USP 2.5 mg (Lot T04769) and ziprasidone HCl capsules 20 mg following a report that some unit dose cartons labeled as ziprasidone were found to contain blister packages labeled as and containing dronabinol capsules. The recalled lot includes cartons that read dronabinol capsules USP 2.5 mg OR ziprasidone hydrochloride capsules 20 mg.

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***
Bacaolinita	Dietary supplement	PEG-40 hydrogenated castor oil

New Product Shortages	***Date Initially Posted***
Rivaroxaban Oral Suspension	6/12/23

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Fluticasone propionate inhalation powder and aerosol (Flovent Diskus and Flovent HFA, GlaxoSmithKline): available for ordering through December 31, 2023	6/2/23
Omacetaxine mepesuccinate injection (Synribo, Teva): no generics are available, patients will require a switch to an alternative treatment	6/13/23
Oxybutynin chloride gel (Gelnique, Abbvie): 100 mg/g; 30 packets in 1 carton (NDC 0023-5861-11) & 100 mg/g; 1 g in 1 PACKET (NDC 0023-5861-10); the metered-dose pump remains available	6/14/23
Glimepiride (Amaryl, Sanofi-Aventis): generics remain available	6/20/23
Interferon beta-1b (Extavia, Novartis): an alternative interferon beta-1b product (Betaseron, Bayer) remains available	6/23/2
Ciprofloxacin and dexamethasone ophthalmic suspension (Cirprodex, Novartis): generics remain available	6/26/23
Tobramycin and dexamethasone ophthalmic suspension (Tobradex, Novartis): generics remain available	6/26/23
Oxandrolone (Oxandrin, Gemini) and oxandrolone generics: FDA withdrew approval	6/28/23

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Glofitamab-gxbm / Columvi / Genentech Inc.	Bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified or large B-cell lymphoma arising from follicular lymphoma, after two or more lines of systemic therapy	6/15/23
Delandistrogene moxeparvovec-rokl / Elevidys / Sarepta Therapeutics Inc.	Gene therapy for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy with a confirmed mutation in the DMD gene	6/22/2
Ritlecitinib / Litfulo/ Pfizer Labs	Kinase inhibitor for the treatment of severe alopecia areata in adults and adolescents 12 years and older	6/23/23
Rozanolixizumab-noli / Rystiggo / UCB, Inc.	Neonatal Fc receptor blocker for the treatment of generalized myasthenia gravis in adults who are anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive	6/26/23
Somatrogon-ghla / Ngenla / Pfizer Labs	Human growth hormone analog for treatment of pediatric patients 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone	6/27/23
Donislecel-jujn / Lantidra / CellTrans Inc	Cell therapy for the treatment of adults with type 1 diabetes who are unable to approach target HbA1c because of repeated episodes of severe hypoglycemia despite intensive diabetes management and education	6/28/23
Valoctocogene roxaparvovec-rvox / Roctavian / BioMarin Pharmaceutical	Gene therapy to treat adults with severe hemophilia A	6/29/23

New Indications:	***Description***	***Date Approved***
Indocyanine green / Spy Agent Green / Novadaq Technologies	For fluorescence imaging of lymph nodes and delineation of lymphatic vessels during lymphatic mapping in adults with breast cancer for which this procedure is a component of intraoperative management	6/5/23
Letermovir / Prevymis / Merck Sharp & Dohme	Prophylaxis of cytomegalovirus disease in adult kidney transplant recipients at high risk (donor CMV seropositive/recipient CMV seronegative)	6/5/23
Linaclotide / Linzess / Abbvie	Treatment of functional constipation in pediatric patients 6 to 17 years of age	6/12/23
Odevixibat / Bylvay / Albireo	The treatment of cholestatic pruritus in patients 12 months of age and older with Alagille Syndrome (ALGS)	6/13/23
Adalumumab-AFZB / Abrilada / Pfizer Inc	Treatment of moderate to severe hidradenitis suppurativa in adult patients.	6/14/23
Empaglflozin / Jardiance / Boehringer Ingelheim	As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus	6/20/23
Empagliflozin; Metformin hydrochloride / Synjardy / Boehringer Ingelheim	As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus	6/20/23
Talazoparib / Talzenna / Pfizer	In combination with enzalutamide for the treatment of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer	6/20/23
Adalimumab-bwwd / Hadlima / Organon LLC	Treatment of moderate to severe hidradenitis suppurativa in adults	6/26/23

New Indications continued:	***Description***	***Date Approved***
Levonorgestrel-releasing intrauterine system / Liletta / AbbVie Inc.	Treatment of heavy menstrual bleeding for up to 5 years in patients who choose intrauterine contraception as their method of contraception	6/29/23
Adalimumab-adbm / Cyltezo / Boehringer Ingelheim	Treatment of non-infectious intermediate, posterior, and panuveitis in adults	6/30/23

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Magnesium sulfate, PEG 3350, potassium chloride, sodium chloride, sodium sulfate / Suflave / Braintree Labs	For oral solution: two bottles and two flavor enhancing packets; osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults, each bottle contains 1 L when reconstituted	6/15/23
Colchicine / Lodoco / Agepha Pharma USA, LLC	Tablet, oral: 0.5 mg; once daily to reduce risk of myocardial infarction, stroke, coronary revascularization, and cardiovascular death in adults with established atherosclerotic disease or with multiple risk factors for cardiovascular disease	6/16/23
Efgartigimod alfa and hyaluronidase-qvfc / Vyvgart Hytrulo / argenx US, Inc.	Injection: 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL single dose vial; administered subcutaneously over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks in the treatment of generalized myasthenia gravis in adults who are anti-acetylcholine receptor antibody positive	6/20/23

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Glofitamab-gxbm / Columvi / Genentech Inc.	
Generic Name / Brand Name / Company	Glofitamab-gxbm / Columvi / Genentech Inc.
Date of approval	6/15/23
Drug Class (Mechanism of Action if novel agent)	Bispecific CD20-directed CD3 T-cell engager
Indication	Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy
Comparative agent – Therapeutic interchange?	Epcoritamab-bysp (Epkinly)
Dosage forms/strengths.	IV infusion: 2.5 mg/2.5 mL or 10 mg/10 mL single dose vial
Common Dose/sig	Follows a step-up dosing schedule: Cycle 1 Day 8, the patient receives 2.5 mg and on Day 15, 10 mg, with both having a 4-hour infusion duration. On Cycle 2, the patient receives 30 mg over a 4-hour infusion duration. Cycles 3-12 include the administration of 30 mg over 2-hour infusion duration.
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	None identified
Clinical Use Evaluation	
Common Adverse Effects	≥20%: cytokine release syndrome (CRS), musculoskeletal pain, rash, fatigue, lymphocyte count decreased, phosphate decreased, neutrophil count decreased, uric acid increased, fibrinogen decreased
Severe Adverse Effects	CRS, neurotoxicity, infection, tumor flare
Severe Drug-Drug Interactions	May inhibit CYP enzymes, leading to increased exposure to CYP substrates
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Complete blood count, uric acid
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	No dosing adjustments recommended
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Potential for CRS, neurologic toxicity, serious infections, tumor flare reactions, and embryo-fetal toxicity.
Special administration technique or considerations	Administer only in a facility equipped to monitor and manage CRS; patients should be hospitalized for the 2.5 mg dose and for subsequent infusions if CRS is experienced with the previous dose. Pretreat with a single obinutuzumab 1000 mg IV dose on Cycle 1, Day 1 (7 days before initiation of glofitamab-gxbm). Premedicate with acetaminophen and an antihistamine before each glofitamab-gxbm dose, and with dexamethasone before the first 4 doses and all subsequent infusions if patient experienced CRS. Ensure adequate hydration. Administered anti-hyperuricemics to patients at risk of tumor lysis syndrome. Consider antiviral and *Pneumocystis jirovecii* pneumonia prophylaxis. Administer as an IV infusion over 2 to 8 hours through a dedicated infusion line with a 0.2-micron in-line filter.
Prepared by	Hagop Margossian
Source	*Columvi* (Glofitamab-gxbm) [prescribing information] San Francisco, CA: Genentech, Inc.; June 2023

Delandistrogene moxeparvovec-rokl / Elevidys / Sarepta Therapeutics Inc.	
Generic Name / Brand Name / Company	Delandistrogene moxeparvovec-rokl / Elevidys / Sarepta Therapeutics Inc.
Date of approval	6/22/23
Drug Class (Mechanism of Action if novel agent)	Gene therapy; delivers gene encoding for micro-dystrophin protein
Indication	Treatment of ambulatory pediatric patients 4 through 5 years of age with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Suspension for IV infusion: nominal concentration of 1.33×10^{13} vector genomes (vg)/mL; provided in a customized kit based on body weight
Common Dose/sig	1.33×10^{14} vg/kg as a single dose
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Eliquis
Clinical Use Evaluation	
Common Adverse Effects	≥5%: vomiting, nausea, liver function test increased, pyrexia, thrombocytopenia
Severe Adverse Effects	Liver injury, severe muscle weakness, myocarditis
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.	Anti-AAVrh74 total binding antigen, liver function, platelet counts, and troponin-I should be assessed prior to infusion. Monitor liver function weekly for the first 3 months after infusion and continue monitoring until all results are unremarkable. Monitor troponin-I weekly for the first month after infusion. Monitor platelet counts weekly for the first 2 weeks.
Used in Pediatric Areas	Approved for patients 4 through 5 years; efficacy not established in patients 3 years and younger or 6 years and older.
Renal or Hepatic Dosing	No renal dose adjustments. Postpone administration in patients with acute liver disease until resolved or controlled. Consider increased risk potential in patients with preexisting liver impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with any deletion in exon 8 and/or exon 9 in the DMD gene. Warnings: Acute serious liver injury: monitor Immune-mediated myositis: patients with deletions in the DMD gene in exons 1 to 17 and/or exons 59 to 71 may be at risk for severe immune-mediated myositis. Additional immunotherapy may be necessary. Myocarditis: monitor Pre-existing immunity against AAVrh74: test at baseline
Special administration technique or considerations	Select patients for treatment who have anti-AAVrh74 total binding antibody titers less than 1:400. Postpone administration in patients with concurrent infection. One day to one week prior to infusion initiate a corticosteroid regimen for a minimum of 60 days. Administer gene therapy as an IV infusion through a peripheral venous catheter over 1 to 2 hours, infusing at a rate of less than 10 mL/kg/hour. Flush with 0.9% sodium chloride injection after infusion.
Prepared by	Terri Levien
Source	Elevidys (delandistrogene moxeparvovec-rokl) [prescribing information]. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2023.

Ritlecitinib / Litfulo/ Pfizer Labs	
Generic Name / Brand Name / Company	Ritlecitinib / Litfulo/ Pfizer Labs
Date of approval	6/23/23
Drug Class (Mechanism of Action if novel agent)	JAK3 Kinase Inhibitor
Indication	Treatment of severe alopecia areata in adolescents (12 years or older) and adults
Comparative agent – Therapeutic interchange?	Baricitinib
Dosage forms/strengths.	Capsules: 50 mg
Common Dose/sig	50 mg capsule by mouth daily with or without food.
DEA Schedule	None
Date of market availability	July 2023
Similar Medication Names	Livalo
Clinical Use Evaluation	
Common Adverse Effects	>1%: headache, diarrhea, acne, rash, urticaria, folliculitis, pyrexia, atopic dermatitis, dizziness, blood creatine phosphokinase increased, herpes zoster, red blood cell count decreased, stomatitis.
Severe Adverse Effects	infection
Severe Drug-Drug Interactions	CYP3A and CYP1A2 inhibitor. Avoid concurrent use with strong CYP3A4 inducers such as rifampin.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Absolute leukocyte count, platelet count, and liver enzymes prior to initiation and during therapy. Screen for viral hepatitis and tuberculosis before initiating.
Used in Pediatric Areas	Efficacy and safety established in patients 12 years and older, but not in patients younger than 12 years
Renal or Hepatic Dosing	No dosage adjustment in renal impairment of in mild or moderate hepatic impairment; not recommended in patients with severe (Child Pugh C) hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with hypersensitivity to ritlecitinib and excipients. Warnings: serious infections, malignancy, major adverse cardiovascular risk, and thrombosis. Avoid using live vaccines during and shortly before treatment. Screen for TB before starting treatment.
Special administration technique or considerations	Swallow capsules whole.
Prepared by	Hagop Margossian
Source	*Litfulo* (Ritlecitinib) [Prescribing Information]. New York, NY: Pfizer Labs; June 2023.

Rozanolixizumab-noli / Rystiggo / UCB, Inc.	
Generic Name / Brand Name / Company	Rozanolixizumab-noli / Rystiggo / UCB, Inc.
Date of approval	6/26/23
Drug Class (Mechanism of Action if novel agent)	Humanized IgG4 monoclonal antibody that binds to neonatal Fc receptor reducing circulating IgG
Indication	Treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive
Comparative agent – Therapeutic interchange?	Efgartigimod alfa (Vyvgart)
Dosage forms/strengths.	Subcutaneous Injection: 280 mg/2 mL (140 mg/ml) single-dose vial
Common Dose/sig	Less than 50 kg: 420 mg dose, 50 to less than 100 kg: 560 mg dose, 100 kg and up: 840 mg dose. All doses are given subcutaneously once a week for 6 weeks. Administer subsequent treatment cycles based on clinical judgement.
DEA Schedule	N/A
Date of market availability	3rd quarter 2023
Similar Medication Names	Ryzodeg
Clinical Use Evaluation	
Common Adverse Effects	≥10%: headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea
Severe Adverse Effects	Aseptic meningitis, infection
Severe Drug-Drug Interactions	Reduced effectiveness of medications that bind to human neonatal Fc receptor
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Confirm anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive
Used in Pediatric Areas	Safety and efficacy not established in pediatric patients
Renal or Hepatic Dosing	No dose adjustment is required for renal impairment. No pharmacokinetic studies have been done for hepatic impairment, but is thought not to affect pharmacokinetics
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Potential for infections, aseptic meningitis, and hypersensitivity reactions. Immunization with live-attenuated or live vaccines is not recommended during therapy with rozanolixizumab-noli. Delay administration in patients with active infection. If serious infection during treatment, consider withholding treatment.
Special administration technique or considerations	Administer as a subcutaneous infusion in the lower right or left part of the abdomen using an infusion pump at a rate of up to 20 mL/hour. The tubing lengths should be 61 cm or shorter and an infusion set with a 26 gauge or larger needle should be used. Do not flush the infusion line. Monitor patients for hypersensitivity reactions during and for 15 minutes after completion of infusion.
Prepared by	Gaige Felix
Source	*Rystiggo* (rozanolixizumab-noli) [prescribing information]. Smyrna, GA: UCB, Inc; June 2023

Somatrogon-ghla / Ngenla / Pfizer Labs	
Generic Name / Brand Name / Company	Somatrogon-ghla / Ngenla / Pfizer Labs
Date of approval	6/27/23
Drug Class (Mechanism of Action if novel agent)	Growth hormone analog
Indication	Treatment of pediatric patients 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone
Comparative agent – Therapeutic interchange?	Somatropin, somapacitan, lonapegsomatropin
Dosage forms/strengths.	Injection: 24 mg/1.2 mL prefilled pen delivering dose is 0.2 mg increments and 60 mg/1.2 mL prefilled pen delivering dose in 0.5 mg increments
Common Dose/sig	0.66 mg/kg based on actual body weight administered once weekly; individualize dose based on growth response
DEA Schedule	None
Date of market availability	August 2023
Similar Medication Names	Somatropin, somapacitan, Engerix
Clinical Use Evaluation	
Common Adverse Effects	>5%: injection site reactions, nasopharyngitis, headache, pyrexia, anemia, cough, vomiting, hypothyroidism, abdominal pain, rash, oropharyngeal pain
Severe Adverse Effects	Hypersensitivity
Severe Drug-Drug Interactions	Glucocorticoids, insulin, and anti-hyperglycemics may require dose adjustment; clearance of CYP 450-metabolized drugs may be altered; oral estrogen may alter somatrogon-ghla clearance
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Periodic glucose and thyroid function tests
Used in Pediatric Areas	Indicated in patients 3 years and older
Renal or Hepatic Dosing	Has not been studied in hepatic or renal impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: acute critical illness, hypersensitivity to drug or excipients, closed epiphyses, active malignancy, diabetic retinopathy, Prader-Willi syndrome. Perform fundoscopic examination prior to initiation to exclude preexisting papilledema. Potential for severe hypersensitivity, increased malignancy risk, glucose intolerance and diabetes mellitus, intracranial hypertension, fluid retention, hypoadrenalism, hypothyroidism, slipped capital femoral epiphysis, progression of preexisting scoliosis, pancreatitis, and lipoatrophy
Special administration technique or considerations	Administer on the same day each week, at any time of day, in the abdomen, thigh, buttocks, or upper arms with rotation of injection sites. If more than one injection is required to deliver a complete dose, each should be administered at a different injection site. If switching from daily growth hormone injections, the once-weekly dose may be initiated the day following their last daily injection.
Prepared by	Terri Levien
Source	Ngenla (somatrogon-ghla) [prescribing information]. New York, NY: Pfizer Labs; June 2023

Donislecel-jujn / Lantidra / CellTrans Inc	
Generic Name / Brand Name / Company	Donislecel-jujn / Lantidra / CellTrans Inc
Date of approval	6/28/23
Drug Class (Mechanism of Action if novel agent)	Allogeneic pancreatic islet cell therapy; secretion of insulin by infused beta cells
Indication	Treatment of adults with type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite diabetes management and education
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Cellular suspension; strength varies between each preparation
Common Dose/sig	Minimum dose is 5,000 EIN/kg for initial infusion and 4,500 EIN/kg for subsequent infusion in the same recipient. A second infusion may be performed if a patient does not achieve independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion.
DEA Schedule	None
Date of market availability	Unknown
Similar Medication Names	Latuda
Clinical Use Evaluation	
Common Adverse Effects	Nausea, fatigue, anemia, diarrhea, abdominal pain, asthenia, headache, URTI, vomiting, UTI
Severe Adverse Effects	90% of subjects had at least one severe adverse reaction. Major causes were attributed to: ○ Infusion procedure: liver laceration/hematoma, hemorrhage, and intra-abdominal bleeding (13%), elevation of portal pressure (7%) ○ Immunosuppression: infection (87%), malignancy (37%)
Severe Drug-Drug Interactions	Avoid systemic steroids
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Blood glucose; monitor blood glucose levels every 15 minutes during infusion and then every 30 minutes for the first 4 to 8 hours after infusion.
Used in Pediatric Areas	Safety and effectiveness have not been established
Renal or Hepatic Dosing	No evidence to support use in patients with liver disease, renal failure, or those who have received a renal transplant.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients for whom immunosuppression is contraindicated. Potential for infections, procedural complications, graft rejection, risks from concomitant immunosuppression, and elevated panel reaction antibodies which may impact candidacy for renal transplant.
Special administration technique or considerations	Infuse only through hepatic portal vein. Do not administer with leukodepleting filters. Measure portal pressure during infusion. Pre-procedural induction immunosuppression should be initiated 30-360 minutes prior to infusion. Monitor patient in hospital for a minimum of 24 hours. Post-infusion medications include PCP and CMV prophylaxis, an anti-IL-2 receptor monoclonal antibody, and a TNF blocker. Immunosuppression must be continued permanently.
Prepared by	Gaige Felix
Source	Lantidra (donislecel-jujn) [prescribing information]. Chicago, IL: CellTrans Inc.; June 2023

Valoctocogene roxaparvovec-rvox / Roctavian / BioMarin Pharmaceutical	
Generic Name / Brand Name / Company	Valoctocogene roxaparvovec-rvox / Roctavian / BioMarin Pharmaceutical
Date of approval	6/29/23
Drug Class (Mechanism of Action if novel agent)	Gene therapy; delivers gene encoding for a form of coagulation factor VIII
Indication	Treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity less than 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Suspension for IV infusion: 2 x 10^{13} vg/mL
Common Dose/sig	6 x 10^{13} vg/kg as a single dose
DEA Schedule	None
Date of market availability	By September 2023
Similar Medication Names	Rocklatan
Clinical Use Evaluation	
Common Adverse Effects	≥5%: nausea, fatigue, headache, infusion-related reactions, vomiting, abdominal pain, liver function test abnormalities
Severe Adverse Effects	Anaphylaxis, hypersensitivity reaction, ALT elevation
Severe Drug-Drug Interactions	Potential interactions with isotretinoin, efavirenz, drugs that interact with corticosteroids, and vaccinations
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Antibodies to adeno-associated virus serotype 5, factor VIII and factor VIII inhibitor presence, and liver function tests at baseline; monitor ALT and factor VIII weekly for at least 26 weeks, then less frequently through year 2 and then every 6 months thereafter; monitor for factor VIII inhibitors
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dose adjustments are recommended for patients with renal or hepatic impairment. Contraindicated in patients with hepatic cirrhosis or fibrosis.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with active infection (acute or uncontrolled chronic), hepatic fibrosis (stage 3 or 4) or cirrhosis, or hypersensitivity to mannitol. Do not administer to patient with a positive test for factor VIII inhibitor. Warnings: Infusion-related reactions: monitor and slow or interrupt infusion as needed; discontinue if anaphylaxis. Hepatotoxicity: monitor and treat with corticosteroids if needed Thromboembolic events: evaluate for risk factors Malignancy: monitor for hepatocellular malignancy including annual liver ultrasound and alpha-fetoprotein testing Reproduction: for 6 months after administration men must not donate semen and men and their female partners must prevent/postpone pregnancy
Special administration technique or considerations	IV infusion through a peripheral vein should be started at 1 mL/min and may be increased every 30 minutes by 1 mL/min up to a maximum rate of 4 mL/min if tolerated. Prime and flush infusion line with 0.9% sodium chloride injection. Administer with high-volume, in-line low protein binding filter with ensured availability of a sufficient number of replacement filters. Monitor for infusion-related reactions during and for at least 3 hours after infusion.
Prepared by	Terri Levien
Source	Roctavian (valoctocogene roxaparvovec-rvox) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; June 2023.