College of Pharmacy and Pharmaceutical Sciences
WASHINGTON STATE UNIVERSITY

Drug Information Center

Highlights of FDA Activities – 7/1/2020 – 7/31/2020

FDA Drug Safety Communications & Drug Information Updates:

Hand Sanitizers: Drug Safety Communications - Risk of Methanol Toxicity & Subpotent Products 7/1 - 7/31/20
The FDA issued several warnings during July regarding hand sanitizer products. Some hand sanitizer products labeled as containing ethanol have tested positive for methanol contamination; others have been labeled to contain methanol. Methanol can be toxic when absorbed through the skin or if ingested. Recent events show that some adults and children have ingested methanol-containing hand sanitizer with adverse events including blindness, hospitalizations, and death. The FDA has also reported the presence of several subpotent hand sanitizer products and products with microbial contamination. The FDA maintains a list of FDA tested and recalled hand sanitizers, and has issued warning letters and import alerts for several products and manufacturers.

Dexamethasone Sodium Phosphate Added to Compounding List – Drug Information Update 7/14/20
To address shortages, the FDA added dexamethasone sodium phosphate to the list of drugs for temporary compounding by outsourcing facilities and pharmacy compounders during the COVID-19 public health emergency.

Discussion of Naloxone Availability – MedWatch Safety Alert 7/23/20
The FDA recommended that health care professionals should discuss the availability of naloxone with all patients who are prescribed opioid pain relievers and consider prescribing it for patients who are increased risk of opioid overdose or if the patient has household members or other close contacts at risk for accidental ingestion or opioid overdose. Labeling for opioid pain medicines and medicines to treatment opioid use disorder will be updated to reflect these recommendations. Naloxone prescribing should also be considered for patients at increased of opioid overdose, even if the patient is not receiving an opioid pain reliever or a medicine to treat opioid use disorder.

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

Metformin HCl Extended-Release Tablets, Granules Pharmaceuticals: Recall – NDMA Impurity 7/6/20
Granules Pharmaceuticals, Inc. recalled twelve lots of metformin HCl extended-release 750 mg tablets due to levels of N-nitrosodimethylamine (NDMA) impurity exceeding acceptable limits. Lot numbers recalled are 4920003A, 4920004A, 4920005A, 4920009A, 4920010A, 4920011A, 4920012A, 4920013SA, 4920014A, 4920015A, 4920016A, and 4920005B. The FDA is maintaining a searchable list of all recalled metformin products.

Daptomycin Injection, Mylan Institutional: Recall - Lack of Sterility 7/7/20
Mylan Institutional LLC recalled Lot No 7605112 of daptomycin injection 500 mg/vial following identification of visible particulates in one vial. Products were distributed between April 2020 and May 2020.

All Clean Hand Sanitizer, Moisturizer and Disinfectant, ITECH 361: Recall – Undeclared Methanol 7/8/20
ITECH 361 recalled one-liter bottles of All Clean Hand Sanitizer, Moisturizer and Disinfectant to the consumer level due to the presence of undeclared methanol. The product (UPC code 6280558370130) was distributed nationwide. The FDA maintains a list of FDA tested and recalled hand sanitizers.

Mystic Shield Protection Topical Solution, Transliquid Technologies: Recall – Undeclared Methanol 7/8/20
Transliquid Technologies LLC recalled 8.45-ounce bottles of Mystic Shield Protection Topical Solution to the consumer level due to the presence of undeclared methanol. The product was distributed from May 21, 2020 to June 30, 2020 in California, Louisiana, Massachusetts, and Texas. The FDA maintains a list of FDA tested and recalled hand sanitizers.

Metformin HCl Extended-Release Tablets, Lupin Pharmaceuticals: Recall – NDMA Impurity 7/8/20
Lupin Pharmaceuticals recalled all batches of metformin HCl extended release 500 mg and 1000 mg tablets due to levels of NDMA impurity exceeding acceptable limits. The FDA is maintaining a searchable list of all recalled metformin products.

Metformin HCl Extended-Release Tablets: Recall – NDMA Impurity 7/13/20
The FDA announced the recall of several additional metformin HCl extended-release tablet products from several manufacturers due to levels of the NDMA impurity exceeding acceptable levels: Avkare (repackager for Amneal, all lots), PD-Rx Pharmaceuticals (repackager for Amneal, 31 lots), PD-Rx Pharmaceuticals (repackager for Marksans, 26 lots), The Harvard Drug Group (repackager for Apotex, one lot T-02134), and Preferred Pharmaceuticals (repackager for Marksans, 4 lots). The FDA is maintaining a searchable list of all recalled metformin products.

Hand Sanitizers, 4e Brands North America: Recall – Undeclared Methanol 7/13 & 7/29
4e Brands North America recalled all lots of all bottle sizes of hand sanitizer to the consumer level due to the presence of undeclared methanol. The products included BLUMEN Advanced Instant Hand Sanitizer Clear, BLUMEN Advanced Hand Sanitizer, BLUMEN Clear LEAR Advanced Hand Sanitizer, BLUMEN Clear Advanced Hand Sanitizer, and BLUMEN Aloe Advanced Hand Sanitizer with 70 Alcohol. The products were distributed nationwide. The FDA maintains a list of FDA tested and recalled hand sanitizers.

BodyGuard® Infusion System Administration Sets, CME America: Recall – Lack of Accuracy 7/14/20
CME America recalled all CME America BodyGuard® Infusion System Administration Sets distributed since May 2016 and used with the BodyGuard® infusion pumps. Testing revealed flow-rate accuracy was not within the specified 5% allowable variance.

bio aaa Advance Hand Sanitizer, AAA Cosmetica, SA de CV: Recall – Undeclared Methanol 7/14/20
AAA Cosmetica, SA de CV recalled all lots of 480 mL bottles of bio aaa Advanced Hand Sanitizer to the consumer level due to the presence of undeclared methanol. The products were distributed nationwide. The FDA maintains a list of FDA tested and recalled hand sanitizers.

Bersih Hand Sanitizer, Soluciones Cosmeticas: Recall – Undeclared Methanol 7/15/20
Soluciones Cosmeticas recalled all lots of 16.9 ounce bottles of Bersih Hand Sanitizer Gel Fragrance Free to the consumer level due to the presence of undeclared methanol. The products were distributed nationwide. The FDA maintains a list of FDA tested and recalled hand sanitizers.

Optimus Instant Hand Sanitizer, LIQ-E SA de CV: Recall – Undeclared Methanol 7/21/20
LIQ-E SA de CV recalled all lots and all bottle sizes of The OPTIMUS Instant Hand Sanitizer to the consumer level due to the presence of undeclared methanol. The products were distributed nationwide. The FDA maintains a list of FDA tested and recalled hand sanitizers.

Dexmedetomidine HCl Injection, Fresenius Kabi: Recall – Contamination with Lidocaine 7/22/20
Fresenius Kabi USA recalled two lots of dexmedetomidine HCl in 0.9% Sodium Chloride Injection, 200 mcg/50 mL (4 mcg/mL), 50 mL fill in a 50 mL vial due to of possible presence of trace amounts of lidocaine. The batch numbers recalled are 6121853 and 6122207, product code is 671050. Products were shipped June 2019 through April 2020.

Hand Sanitizers, Real Clean Distribuciones SA de CV: Recall – Undeclared Methanol 7/24/20
Real Clean Distribuciones SA de CV recalled all lots of Born Basic ANTI-BAC HAND SANITIZER, Scent Theory KEEP CLEAN Moisturizing Hand Sanitizer, Scent Theory KEEP IT CLEAN Moisturizing Hand Sanitizer, and Lux Eoi Hand Sanitizing Gel to the consumer level due to the presence of undeclared methanol. The products were distributed nationwide. The FDA maintains a list of FDA tested and recalled hand sanitizers.

Herbacil Antiseptic Hand Sanitizers, Broncolin SA de CV: Recall – Undeclared Methanol 7/28/20
Broncolin SA de CV recalled all lots of Herbacil Antiseptic Hand Sanitizer 70% Alcohol in 4 bottle sizes to the consumer level due to the presence of undeclared methanol. The products were distributed nationwide. The FDA maintains a list of FDA tested and recalled hand sanitizers.

Hand Sanitizers, MXL Commercial SA de CV: Recall – Undeclared Methanol and Subpotency 7/28/20
Resource Recovery and Trading LLC recalled all lots of hand sanitizer manufactured by Commercial SA de CV and labeled as HAND SANITIZER 70% Ethyl Alcohol Disinfectant Gel 6.7 ounce bottles and HAND SANITIZER Non-sterile Solution 70% Topical Solution in 20 L containers to the consumer level due to the presence of undeclared methanol and subpotent ethyl alcohol. The products were distributed nationwide. The FDA maintains a list of FDA tested and recalled hand sanitizers.

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	*Undeclared Ingredient(s) or Contaminants*
Hemp Oil Products from InHe Manufacturing and MHR Brands*	Lead
Iron drops from Wellments LLC*	Milk allergen
KORE ORGANIC Watermelon CBD Oil Tincture*	Lead
Sundial Herbal Products*	Misbranded; labeling contains drug claims

*recalled

New Product Shortages	*Date Initially Posted*
Doxycycline Hyclate Injection	7/10/20
Leuprolide Acetate Injection	7/24/20

Sole Source or Branded Product Discontinuations/Withdrawals	*Date Posted*
Ergotamine Tartrate and Caffeine Tablets (Cafergot, Sandoz); ergotamine tartrate and caffeine tablets remain available from other manufacturers	7/2/20
Somatropin Recombinant Injection (Humatrope, Eli Lilly and Co) 5 mg kit; the 6 mg, 12 mg, and 24 mg vials remain available	7/8/20
Adalimumab Pre-filled syringes (Humira, AbbVie) 10 mg/0.2 mL and 20 mg/0.4 mL; 10 mg/0.1 mL, 20 mg/0.2 mL pre-filled syringes remain available, as well as 40 mg and 80 mg syringes and pens	7/27/20
Mesalamine Suppositories (Canasa, Allergan) 1 g in boxes of 42; 500 mg and 1 g suppositories remain available in other package sizes and from other manufacturers	7/30/20

New Drug Approvals:	*Description (See Attached Drug Summaries)*	*Date Approved*
Fostemsavir tromethamine / Rukobia / ViiV Healthcare	Gp120-directed attachment inhibitor for the treatment of multidrug-resistant HIV in treatment-experienced adults	7/2/20
Remimazolam / Byfavo / Cosmo Technologies	Benzodiazepine for induction and maintenance of procedural sedation in adults undergoing short procedures	7/2/20
Decitabine, cedazuridine / Inqovi / Astex Pharmaceuticals	Formulation allowing oral dosing of decitabine for treatment of adults with myelodysplastic syndromes and chronic myelomonocytic leukemia	7/7/20
Abametapir / Xeglyze / Groupe Parima Inc.	Pediculicide for topical treatment of head lice infestation in patients 6 months and older.	7/24/20
Brexucabtagene autoleucel / Tecartus / Kite Pharma Inc	Autologous CAR-T cell therapy for the treatment of adult patients with mantle cell lymphoma; available through a restricted REMS program	7/24/20
Tafasitamab-cxix / Monjuvi / Morphosys	CD19-directed cytolytic antibody for use with lenalidomide in treatment of patients with diffuse large B-cell lymphoma not eligible for autologous stem cell transplant	7/31/20

New Indications:	***Description***	***Date Approved***
Guselkumab / Tremfya / Janssen Biotech Inc.	Treatment of adult patients with active psoriatic arthritis	7/13/20
Olopatadine HCl ophthalmic solution 0.7% / Pataday Once Daily Relief / Alcon	Switched from prescription to over-the-counter availability for eye allergy itch relief	7/13/20
Capsaicin 8% patch / Qutenza / Averitas Pharma, Inc.	Treatment of neuropathic pain associated with diabetic peripheral neuropathy of the feet	7/17/20
Calcitriol ointment 3 mcg/g / Verctical / Galderma Laboratories	Indication expanded to include treatment of mild to moderate plaque psoriasis in patients 2 years and older	7/17/20
Atezolizumab / Tecentriq / Genentech	In combination with cobimetinib and vemurafenib for the treatment of patients with unresectable or metastatic BRAF V600 mutation positive melanoma	7/30/20
Cannabidiol / Epidiolex / GW Research	Treatment of seizures associated with tuberous sclerosis complex in patients 1 year and older, and expansion of indication for treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome to patients 1 year and older	7/31/20
Atazanavir, cobicistat / Evotaz / Bristol-Myers Squibb	Indication expanded to include use in the treatment of HIV in pediatric patients weighing at least 35 kg	7/31/20
Darunavir, cobicistat / Prezcobix / Janssen Products	Indication expanded to include use in the treatment of HIV in pediatric patients weighing at least 40 kg	7/31/20

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Trace elements / Tralement / American Regent	IV solution: cupric sulfate (copper 0.3 mg/mL), manganese sulfate (manganese 55 mcg/mL), selenious acid (selenium 60 mcg/mL), zinc sulfate (zinc 3 mg/mL) indicated for adult and pediatric patients weighing at least 10 kg as a source of trace elements for parenteral nutrition	7/2/20
Collagenase clostridium histolyticum-aaes / Qwo / Endo Global Aesthetics	Injection: 0.92 mg or 1.84 mg as lyophilized powder; for the treatment of moderate to severe cellulite in the buttocks of adult women	7/6/20
Oxymetazoline / Upneeq / RVL Pharmaceuticals	Ophthalmic solution 0.1%; for the treatment of acquired blepharoptosis in adults	7/8/20
Calcipotriene, betamethasone dipropionate / Wynzora / MC2	Topical cream: 0.064%, 0.005%; for the treatment of plaque psoriasis in adults	7/20/20
Calcium, magnesium, potassium, and sodium oxybates / Xywav / Jazz Pharmaceuticals	Oral solution: 0.5 g/mL total salts; for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years and older with narcolepsy	7/21/20
Budesonide, formoteroll fumarate, glycopyrrolate inhalation / Breztri Aerosphere / AstraZeneca	Metered aerosol; for the maintenance treatment of patients with chronic obstructive pulmonary disease	7/23/20

Compiled by:

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Fostemsavir tromethamine / Rukobia / ViiV Healthcare	
Generic Name / Brand Name / Company	Fostemsavir tromethamine / Rukobia / ViiV Healthcare
Date of approval	7/2/20
Drug Class (Mechanism of Action if novel agent)	gp120-directed attachment inhibitor; binds gp120 subunit within HIV-1 envelope glycoprotein and inhibits interaction between virus and cellular CD4 receptors, thus preventing attachment
Indication	In combination with other antiretroviral agents for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current regimen due to resistance, intolerance, or safety considerations
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Extended-release tablet: 600 mg
Common Dose/sig	600 mg orally twice daily
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Fosamprenavir, Rubraca
Clinical Use Evaluation	
Common Adverse Effects	≥5%: nausea
Severe Adverse Effects	Immune reconstitution inflammatory syndrome
Severe Drug-Drug Interactions	Contraindicated with strong CYP3A inducers (eg, enzalutamide, carbamazepine, phenytoin, rifampin, mitotane, St. John's wort) Avoid ethinyl estradiol dose exceeding 30 mcg daily Caution with drugs known to prolong QT interval
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver chemistries in patients with hepatitis B and/or C co-infection
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment necessary in patients with renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: • Hypersensitivity • Coadministration with strong CYP450 3A inducers Warnings: • Immune reconstitution syndrome • QTc prolongation with higher than recommended doses • Elevations in hepatic transaminases in patients co-infected with hepatitis B and/or C
Special administration technique or considerations	Swallow tablets whole; do not crush, chew or split. May take with or without food.
Prepared by	Terri Levien
Source	Rukobia (fostemsavir) [prescribing information]. Research Triangle Park, NC: ViiV Healthcare; July 2020.

Remimazolam / Byfavo / Arcadia Pharma, Inc.	
Generic Name / Brand Name / Company	Remimazolam / Byfavo / Arcadia Pharma, Inc.
Date of approval	7/2/20
Drug Class (Mechanism of Action if novel agent)	Benzodiazepine
Indication	Sedation in adults for procedures lasting 30 minutes or less
Comparative agent – Therapeutic interchange?	Midazolam and propofol

Dosage forms/strengths	Single dose vial powder for reconstitution with 20 mg of remimazolam which is equivalent to 27.2 mg of remimazolam besylate
Common Dose/sig	Standard adult patients: receive an initial dose of a 5 mg IV push over a 1-minute period. Then, if necessary, for maintenance administer a 2.5 mg dose IV over a 15-minute-time-period. Wait at least 2 minutes between maintenance doses. ASAPS III-IV patients (at the discretion of the physician): Administer the initial dose as a 2.5 to 5 mg IV push injection over a 1-minute period. Then, if necessary, for maintenance administer a 1.25 to 2.5 mg dose IV over a 15-minute-time-period. Wait at least 2-minutes between maintenance doses.
DEA Schedule	To be determined after DEA review
Date of market availability	Marketing may not occur until after the DEA has determined scheduling, which is expected in the next few months.
Similar Medication Names	Midazolam, remifentanil
Clinical Use Evaluation	
Common Adverse Effects	>10%: Hypotension, hypertension, diastolic hypertension, systolic hypertension, hypoxia, diastolic hypotension
Severe Adverse Effects	Hypoxia, bradycardia, hypotension
Severe Drug-Drug Interactions	Whenever a benzodiazepine is used in conjunction with an opioid analgesic, other benzodiazepines, or propofol caution needs to be taken due to combined CNS effects. Patients should be continuously monitored for respiratory depression and depth of sedation.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and effectiveness have not been established for patients younger than 18 years old; remimazolam should not be used in this population.
Renal or Hepatic Dosing	In patients with severe hepatic impairment the dose should be carefully titrated to effect; reduced doses might be indicated. Dosage adjustments are not required in patients with renal impairment or mild to moderate hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Hypersensitivity Warnings and Precautions: • Hypersensitivity reactions including anaphylaxis may occur • Neonatal Sedation: The use of benzodiazepines during later stages of pregnancy can result in neonatal sedation. Observe newborn for sedation and manage appropriately. • Pediatric Neurotoxicity: In animal studies exposure longer than 3 hours was associated with neurotoxicity. Weigh benefits against risks if considering use for elective procedures in children under 3 years old.
Special administration technique or considerations	The product must be prepared immediately before use; reconstituted with 8.2 mL sterile 0.9% sodium chloride injection. Only personnel trained in the administration of procedural sedation and not involved in the diagnostic or therapeutic procedure should administer remimazolam. Vital signs must be continuously monitored during sedation and through the recovery period. Resuscitative drugs with patient appropriate equipment for assisted ventilation must be immediately available. Administer supplemental oxygen to sedated patients through the recovery period.
Prepared by	Jeremiah Salmond
Source	Byfavo (remimazolam) [prescribing information]. Indianapolis, IN: Acadia Pharma, Inc; July 2020.

Decitabine and cedazuridine/ Inqovi / Otsuka Pharmaceutical Company, Ltd.	
Generic Name / Brand Name / Company	Decitabine and cedazuridine / Inqovi / Otsuka Pharmaceutical Company, Ltd.
Date of approval	7/7/20
Drug Class (Mechanism of Action if novel agent)	Nucleoside metabolic inhibitor and cytidine deaminase inhibitor; administration of cedazuridine allows for oral decitabine administration
Indication	Adult patients with myelodysplastic syndromes (MDS)
Comparative agent – Therapeutic interchange?	Azacitidine, decitabine, lenalidomide, and daunorubicin and cytarabine
Dosage forms/strengths	Tablets: 35 mg decitabine and 100 mg cedazuridine
Common Dose/sig	One tablet by mouth once daily on days 1 through 5 of each 28-day cycle
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Decitabine, Invokana
Clinical Use Evaluation	
Common Adverse Effects	≥20%: Fatigue, constipation, hemorrhage, myalgia, mucositis, arthralgia, nausea, dyspnea, diarrhea, rash, dizziness, febrile neutropenia, edema, headache, cough, decreased appetite, upper respiratory tract infection, pneumonia, and transaminase increased. Common laboratory abnormalities include leukocytes decreased, platelet count decreased, neutrophil count decreased, and hemoglobin decreased.
Severe Adverse Effects	Febrile neutropenia, pneumonia, sepsis, septic shock, respiratory failure, cerebral hemorrhage, and sudden death
Severe Drug-Drug Interactions	Drugs metabolized by cytidine deaminase (CDA): cedazuridine is an inhibitor of cytidine deaminase enzyme. Co administration of drugs metabolized by CDA may result in increased systemic exposure.
Severe Drug-Food Interactions	Must be taken on an empty stomach.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Obtain completed blood cell counts before each cycle of treatment and initiation of decitabine/cedazuridine. • Absolute neutrophil count must be ≥1,000/mcL • Platelets must be ≥50,000/mcL
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment is necessary in mild to moderate renal impairment. Monitor patients with moderate renal impairment (Crcl 30-59 mL/min) for adverse reactions. The combination has not been studied in patients with severe renal impairment (Crcl 15-29) or end-stage renal disease (ESRD Crcl <15 mL/min). The effects of moderate or severe hepatic impairment have not been assessed.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity to decitabine, cedazuridine, or any ingredients Warnings: • Myelosuppression: fatal myelosuppression can occur; dose reductions and dosing delays are recommended for myelosuppression • Embryo-fetal toxicity: decitabine/cedazuridine can cause fetal harm when administered to pregnant woman.
Special administration technique or considerations	Medication should be dispensed in original packaging. Tablets should be swallowed whole; not chewed, cut or crushed. Doses should be taken at the same time each day. Food should not be consumed 2 hours before or after each dose.
Prepared by	Vanessa Tuy
Source	Inqovi (decitabine and cedazuridine) [prescribing information]. Princeton, NJ: Otsuka Pharmaceutical Company, Ltd; July 2020.

Abametapir / Xeglyze / Groupe Parima Inc.	
Generic Name / Brand Name / Company	Abametapir / Xeglyze / Groupe Parima Inc.
Date of approval	7/24/20
Drug Class (Mechanism of Action if novel agent)	Pediculicide; metalloproteinase inhibitor
Indication	Topical treatment of head lice infestation in patients 6 months and older.
Comparative agent – Therapeutic interchange?	Pediculoides
Dosage forms/strengths	Lotion: 0.74% (w/w) in single-use 210 mL glass bottle
Common Dose/sig	Apply to dry hair to thoroughly coat the hair and scalp. Massage into the scalp and throughout hair. Leave on the hair and scalp for 10 minutes, then rinse off with warm water.
DEA Schedule	None
Date of market availability	Not determined
Similar Medication Names	Abacavir, Xeljanz
Clinical Use Evaluation	
Common Adverse Effects	≥1%: erythema, rash, skin burning sensation, contact dermatitis, vomiting, eye irritation, and hair color changes.
Severe Adverse Effects	None
Severe Drug-Drug Interactions	Avoid administration of drugs that are substrates of CYP3A4, 2B6, or 1A2 within 2 weeks after application of abametapir.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and effectiveness have been established in pediatric patients 6 months of age and older. Safety and effectiveness have not been established in pediatric patients below the age of 6 months.
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity to abametapir or inactive ingredients (benzyl alcohol, butylated hydroxytoluene, carbomer 980, light mineral oil, polysorbate 20, trolamine, and water) Warnings: • Neonatal benzyl alcohol toxicity: Systemic exposure to benzyl alcohol has been associated with serious and fatal adverse reactions including "gasping syndrome" (CNS depression, metabolic acidosis, and gasping respirations) in neonates and low birth weight infants. • Benzyl alcohol toxicity from accidental ingestion: To prevent accidental ingestion in pediatric patients, administer under direct supervision of an adult. Ingestion of benzyl alcohol in large quantities may result in GI (nausea, vomiting, diarrhea) and CNS (headache, ataxia, convulsions, coma) adverse reactions.
Special administration technique or considerations	Administration: • Shake well before use. • Wash hands after application of abametapir. • Do not flush unused contents down sink or toilet. • Avoid contact with eyes. • Do not ingest. • Hair may be shampooed any time after treatment.
Prepared by	Vanessa Tuy
Source	Xeglyze (abametapir) [prescribing Information]. Princeton, NJ: Groupe Parima Inc.; June 2020.

Tafasitamab-cxix / Monjuvi / MorphoSys US	
Generic Name / Brand Name / Company	Tafasitamab-cxix / Monjuvi / MorphoSys US
Date of approval	7/31/20
Drug Class (Mechanism of Action if novel agent)	Humanized CD19-directed cytolytic monoclonal antibody; binds CD19 antigen on pre-B and mature B lymphocytes and B-cell malignancies, mediating B-cell lysis through apoptosis and immune effector mechanisms
Indication	In combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma who are not eligible for autologous stem cell transplant
Comparative agent – Therapeutic interchange?	CAR-T therapies
Dosage forms/strengths	Injection: 200 mg as lyophilized powder in single-dose vial
Common Dose/sig	12 mg/kg as an IV infusion on days 1, 4, 8, 15 and 22 of the first 28-day cycle, days 1, 8, 15, and 22 of the second and third 28-day cycle, and days 1 and 15 of each subsequent 28-day cycle. Administer with lenalidomide therapy for a maximum of 12 cycles, then continue tafasitamab as monotherapy until disease progression or unacceptable toxicity.
DEA Schedule	None
Date of market availability	Expected to be available “shortly”
Similar Medication Names	Tafamidis
Clinical Use Evaluation	
Common Adverse Effects	≥20%: neutropenia, fatigue, anemia, diarrhea, thrombocytopenia, cough, pyrexia, peripheral edema, respiratory tract infection, decreased appetite
Severe Adverse Effects	Neutropenia, anemia, thrombocytopenia, febrile neutropenia, fatigue, pyrexia, diarrhea, cough, dyspnea, respiratory tract infections, urinary tract infection, bronchitis, hypokalemia, back pain
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.	Complete blood cell count prior to each treatment cycle and throughout treatment
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No adjustments recommended. Pharmacokinetics were not altered in patients with mild to moderate renal impairment or mild hepatic impairment. The effects of severe renal impairment and moderate to severe hepatic impairment have not been assessed.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Therapy should be permanently discontinued for severe infusion related reactions. Warnings: • Infusion-related reactions • Myelosuppression • Infections • Embryo-fetal toxicity
Special administration technique or considerations	Should be administered by a healthcare professional with immediate access to emergency equipment and support to manage infusion-related reactions. Administer premedications which may include acetaminophen, histamine H1 receptor antagonists, histamine H2 receptor antagonists, and/or glucocorticosteroids, 30 minutes to 2 hours prior to initiating the tafasitamab infusion; premedication is optional if no reaction is observed after the first 3 infusions.

	Administered as an IV infusion. Initiated at a rate of 70 mL/h for the first 30 minutes, then increased so the infusion is completed within 1.5 to 2.5 hours. Subsequent infusions should be administered over 1.5 to 2 hours. Dose adjustments are recommended for infusion-related reactions and myelosuppression.
Prepared by	Terri Levien
Source	Monjuvi (tafasitamab-cxis) [prescribing information]. Boston, MA: Morphosys US Inc; July 2020.