Highlights of FDA Activities – 1/1/15 – 1/31/15

FDA Drug Safety Communications & Drug Information Updates:

Prescription and Over-the-Counter Pain Medicines: FDA Review of Possible Risks of Pain Medicine Use During Pregnancy 1/9/15

Following recent reports questioning the safety of prescription and OTC medications in pregnancy, the FDA reviewed published studies and determined they are too limited to provide any recommendations at this time. The use of pain medications should be carefully considered in pregnancy, weighing the risks of untreated pain with the potential risks of medication use.

Bone Graft Substitutes Containing Recombinant Proteins or Synthetic Peptides in Patients Under 18 Years: Reports of Serious Injuries 1/21/15

The FDA is recommending against the routine use of bone graft substitutes containing recombinant proteins or synthetic peptides in patients younger than 18 years because their safety and effectiveness have not been evaluated in this population. These products have been associated with serious injuries, including excess bone growth, fluid accumulations, inhibited bone healing, and swelling. Alternatives should be considered before using these products. If these products are used, parents/guardians and patients should be informed about the risks and benefits of their use.

Major Product Recalls Announced Through MedWatch:

Virazole (Ribavirin Powder for Solution) by Valeant Pharmaceutical North America, LLC: Recall - Due to Microbial Contamination 1/2/15

Valeant Pharmaceuticals North America LLC (VPNA) has issued a voluntarily recall of one lot of Virazole (ribavirin powder for solution), 100 mL, 6 g vial, 4-pack with an NDC of 00187-0007-14 to the user level due to microbial contamination. The affected Virazole lot, No. 340353F with an expiration date of Oct-2018, was distributed in the U.S. and Australia.

Wallcur Practi-0.9% Sodium Chloride-IV Bags 50 mL, 250 mL, 500 mL, and 1000 mL and Wallcur Practi-0.9% Sodium Chloride-IV Bag with Distilled Water 100 mL 1/12/15

Recalled following administration of these products intended for training, simulation, and educational purposed only. The products are not intended for human or animal administration, and are not sterile.

Hospira – 0.9% Sodium Chloride Injection, USP, 250 mL – Particulate Matter 1/23/15

Hospira, Inc has issued a voluntary nationwide recall of one lot of 0.9% Sodium Chloride Injection, USP, 250 mL with an NDC of 0409-7983-02 to the user level due to one confirmed customer report of particulate (human hair) in a single unit. The affected product Lot 44-002-JT with an expiration date Aug-2016.

Dietary Supplement Recalls & Public Notifications

In January, the FDA issued notifications to the public regarding undeclared active ingredients in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Hidden/Undeclared Drug Ingredient(s)***
Happy Passengers	Sexual enhancement	Sildenafil

New Product Shortages Reported by the FDA:	***Date Initially Posted***
Dimercaprol (Bal-in-Oil) injection	1/8/15
Fluoxymesterone (Androxy) 10 mg tab	1/15/15
Nebivolol (Bystolic, Forest Laboratories) 20 mg tablets	1/23/15
Methylene blue injection (Akorn Pharmaceuticals) 10 mg/mL	1/29/15

Product Discontinuations/Withdrawals	***Date Posted***
Imipenem/cilastatin (Primaxin 250 mg and Primaxin 500 mg ADD-Vantage Vials) Only the ADD-Vantage presentation is being discontinued; other Primaxin and generic vials remain available.	1/6/15
Boceprevir (Victrelis, Merck Sharp & Dohme) 200 mg capsules Estimated availability until December 2015; alternative anti-hepatitis C antivirals include telaprevir, sofosbuvir, sofosbuvir/ledipasvir, and simeprevir.	1/20/15

New Drug Approvals:	***Description***	***Date Approved***
Edoxaban / Savaysa / Daiichi Sankyo	See attached drug summary	1/8/15
Secukinumab / Cosentyx / Novartis	See attached drug summary	1/21/15
Soluble ferric pyrophosphate / Triferic / Rockwell Medical	See attached drug summary	1/23/15
Parathyroid hormone / Natpara / NPS Pharms	See attached drug summary	1/23/15
Meningococcal group B vaccine / Bexsero / Novartis	See attached drug summary	1/23/15

New Indications:	***Description***	***Date Approved***
Ibrutinib / Imbruvica / Pharmacyclics & Janssen Biotech	Treatment of Waldenström's macroglobulinemia	1/29/15
Fluticasone propionate lotion 0.05% / Cutivate / Fougera	Atopic dermatitis indication expanded to include use in patients 3 months of age and older	1/16/15
Lisdesamfetamine / Vyvanse / Shire	Treatment of binge-eating disorder in adults	1/30/15

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Carbidopa-levodopa extended-release capsule / Rytary / Impax Labs	Extended-release capsule dosed three times daily in management of Parkinson's disease and parkinsonism	1/7/15
Neostigmine methylsulfate injection / Fresenius Kabi USA	For reversal of the effect of nondepolarizing neuromuscular blocking agents after surgery.	1/8/15
Carbidola and levodopa enteral suspension / Duopa / Abbvie	See attached drug summary	1/13/15
Phoxillum Renal Replacement Solutions / Baxter	Replacement solution in continuous renal replacement therapy	1/13/15
Phenylephrine HCl 2.5% and 10% ophthalmic solution / Akorn	For pupil dilation before ocular examinations; does not require refrigeration	1/15/15
Perindopril arginine and amlodipine besylate tablet / Prestalia / Symplmed Pharms	Treatment of hypertension in patients not adequately controlled on monotherapy or as initial therapy in patients likely to need multiple drugs to achieve blood pressure goals	1/21/15
Atazanavir 300 mg and cobicistat 150 mg tablets / Evotaz / Bristol Myers Squibb	Use in combination with other antiretroviral agents for the treatment of HIV-1 infection	1/29/15
Darunavir 800 mg and cobicistat 150 mg tablet / Prezcobix / Janssen	Use in combination with other antiretroviral agents for the treatment of HIV-1 infection	1/29/15
Empagliflozin and linagliptin tablet / Glyxambi / Boehringer Ingelheim	Combination SGLT2 inhibitor and DPP-4 inhibitor for management of type 2 diabetes	1/30/15
Hydrocodone extended-release capsules / Zohydro ER / Zogenix	New formulation with abuse-deterrent properties	1/30/15

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Ferric Pyrophosphate Citrate Solution / Triferic / Rockwell Medical, Inc.	
Generic Name / Brand Name / Company	Ferric pyrophosphate citrate solution / Triferic / Rockwell Medical, Inc.
Date of approval	January 23, 2015
Drug Class (Mechanism of Action if novel agent)	Iron replacement agent in the form of ferric pyrophosphate citrate that is added to hemodialysate and binds to transferrin for transport prior to being incorporated into hemoglobin molecules.
Indication	Iron replacement and hemoglobin maintenance in patients with hemodialysis-dependent chronic kidney disease and not undergoing hemodialysis at home or peritoneal dialysis.
Comparative agent – Therapeutic interchange?	None; alternative to oral or intravenous iron replacement
Dosage forms/strengths. Common Dose/sig	Ampule: 27.2 mg of iron per 5 mL of solution (5.44 mg/mL). Dose: one ampule of ferric pyrophosphate citrate (27.2 mg of iron) should be added to 2.5 gallons of bicarbonate concentrate to create a 2 micromolar concentration (110 mcg/L); additional ampules can be added to bicarbonate concentrate in the ratio of one ampule per 2.5 gallons of bicarbonate solution. Administer at each dialysis procedure.
DEA Schedule	Not scheduled
Date of market availability	1st Quarter of 2015
Similar Medications (Look-Alike Sound-Alike)	Teriparatide, Trafermin, Travert, Treprostinil, Triprolidine, Ferrex, Ferric carboxymaltose, ferric citrate, ferric subsulfate, ferric sulfate
CLINICAL USE EVALUATION	
Common Adverse Effects	Procedural hypotension, muscle spasms, headache, pain in extremity, peripheral edema, dyspnea, pyrexia, back pain, urinary tract infections, asthenia, fatigue, arteriovenous fistula thrombosis and hemorrhage
Severe Adverse Effects	Hypersensitivity reactions
Severe Drug-Drug Interactions	No known drug-drug interactions at this time
Severe Drug-Food Interactions	No known drug-food interactions at this time
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	The patient's iron status should be tested via pre-dialysis blood samples as post-dialysis testing may overestimate the serum iron levels and transferrin saturation.
Used in Pediatric Areas	Safety and efficacy in pediatric populations have not been established
Renal or Hepatic Dosing	Only indicated for use in patients with hemodialysis-dependent chronic kidney disease. No dosage adjustments necessary in hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• There are currently no contraindications to the use of ferric pyrophosphate citrate. • Patients should be monitored for any signs and/or symptoms of hypersensitivity reactions.

	• Iron laboratory testing should be performed on pre-dialysis samples as post-dialysis samples may overestimate serum iron levels as well as transferrin saturation.
Special administration technique or considerations	• One ampule should be added directly to 2.5 gallons of bicarbonate concentrate. Multiple ampules can be utilized at the ratio of one ampule per 2.5 gallons of bicarbonate concentrate. • Ferric pyrophosphate citrate should not be added to acid concentrate mixtures.
Prepared by	Ross Bindler, PharmD

Recombinant Human Parathyroid Hormone for Injection / Natpara / NPS Pharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Recombinant human parathyroid hormone for injection / Natpara / NPS Pharmaceuticals, Inc.
Date of approval	January 23, 2015
Drug Class (Mechanism of Action if novel agent)	Parathyroid hormone increases patient's serum calcium concentration by: 1. increasing renal tubular reabsorption of calcium, 2. increasing intestinal calcium absorption, and 3. increasing bone turnover which releases calcium into circulation.
Indication	Recombinant human parathyroid hormone is indicated as an add-on to calcium and vitamin D supplementation to control hypocalcemia in patients diagnosed with hypoparathyroidism. It has not been studied in patients with hypoparathyroidism that is due to calcium-sensing receptor mutations or acute hypoparathyroidism following surgery.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Available in four dosage strengths in multiple-dose, dual-chamber glass cartridges for use in Q-Cliq pens. The cartridges contains sterile powder and diluent to supply 25 mcg per dose, 50 mcg per dose, 75 mcg per dose , or 100 mcg per dose. The dose of recombinant human parathyroid hormone is individualized for each patient based on total serum albumin-corrected calcium level as well as 24-hour urinary calcium excretion. It should be initiated at 50 mcg per day as a subcutaneous injection in the thigh, alternate thigh daily; the goal should be to maintain albumin-corrected total serum calcium within the lower half of the normal range (i.e. 8 to 9 mg/dL) without need for active vitamin D administration. The dose may be increased by 25 mcg every 4 weeks up to the maximum of 100 mcg if serum calcium cannot be normalized above 8 mg/dL without administration of an active form of vitamin D and/or oral calcium; the dose may be decreased to as low as 25 mcg per day if the serum calcium is regularly above 9 mg/dL after active vitamin D administration is discontinued and calcium decreased to meet the patient's daily requirements.
DEA Schedule	Not scheduled
Date of market availability	2nd Quarter of 2015; available only thru restricted REMS program
Similar Medications (Look-Alike Sound-Alike)	Natafort, Natatab, other parathyroid hormone based medications
CLINICAL USE EVALUATION	
Common Adverse Effects	Paraesthesia, hypocalcemia, headache, hypercalcemia, nausea, hypoesthesia, diarrhea, vomiting, arthralgia, hypercalciuria, pain in the extremities, upper respiratory tract infections, upper abdominal pain, sinusitis, decreased active vitamin D blood levels, hypertension, facial hypoesthesia and neck pain

Severe Adverse Effects	Osteosarcoma, hypercalcemia, hypocalcemia, production of anti-PTH antibodies
Severe Drug-Drug Interactions	Alendronate (hypocalcemia) and digoxin (digitalis toxicity due to rise in serum calcium/hypercalcemia)
Severe Drug-Food Interactions	Patients should have adequate intake of calcium and vitamin D. If the patient is taking active vitamin D, the dose should be reduced by 50% prior to initiation of therapy if their serum calcium is greater than 7.5 mg/dL.
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Serum calcium concentration, 24-hour urinary calcium excretion, renal function tests, serum albumin level to calculate corrected calcium, serum active vitamin D levels
Used in Pediatric Areas	Safety and efficacy have not been established; use in patients with open epiphyses should be avoided due to increased osteosarcoma risk.
Renal or Hepatic Dosing	Inadequate number of patients with moderate to severe renal impairment to determine if the efficacy or safety of the medication would be different. Since some of the mechanisms of action of recombinant human parathyroid hormone are dependent on renal function and the drug is eliminated by the kidneys caution is advised. There are no specific dose reductions for patients with hepatic dysfunction.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Vitamin D and calcium supplementation should be actively adjusted based on serum calcium concentration 3 to 7 days after starting treatment. • Increased risk of osteosarcoma (REMS program)
Special administration technique or considerations	• The Q-Cliq pen containing the remaining doses should be stored in the refrigerator; do not freeze • The Q-Cliq pen, which can be used for up to 2 years of daily treatment, is designed for use with a 31G and 8 mm BD Ultra-Fine Pen Needle • Reconstituted medication cartridges older than 14 days must not be used
Prepared by	Ross Bindler, PharmD

Edoxaban / Savaysa / Daiichi Sankyo Co.	
Generic Name / Brand Name / Company	Edoxaban / Savaysa / Daiichi Sankyo Co.
Date of approval	January 8, 2015
Drug Class (Mechanism of Action if novel agent)	Factor Xa inhibitor
Indication	• Reduce the risk of stroke and systemic embolism in patients with non-valvular-atrial-fibrillation (NVAF) and CrCl of 95 mL/min or less. • Treatment of deep-vein thrombosis (DVT) and pulmonary embolism (PE) after 5-10 days of initial therapy with a parenteral anticoagulant
Comparative agent – Therapeutic interchange?	Apixaban (Eliquis), rivaroxaban (Xarelto)
Dosage forms/strengths. Common Dose/sig	Tablets: 60 mg, 30 mg, 15 mg NVAF dose: • CrCl >95 mL/min: Use not recommended in this population • CrCl 50-95 mL/min: 60 mg orally once daily • CrCl 15-50 mL/min (or body weight less than 60 kg): 30 mg orally once daily For the treatment of DVT and PE (after initial treatment with a parenteral anticoagulant): • 60 mg by mouth once daily • If CrCl 15-50 mL/min (or body weight less than 60 kg): 30 mg orally once daily

DEA Schedule	Not Scheduled
Date of market availability	February 2015
Similar Medications (Look-Alike Sound-Alike)	Etidocaine, etodolac
CLINICAL USE EVALUATION	
Common Adverse Effects	Non-major bleeding, anemia, elevated LFTs, rash
Severe Adverse Effects	Major bleeding
Severe Drug-Drug Interactions	Increased risk of bleeding: • Anticoagulants – avoid concomitant use • Aspirin, other anti-platelets, and thrombolytics • Chronic use of nonsteroidal anti-inflammatory drugs (NSAIDS) Decreased efficacy: • Rifampin (P-gp inducer) – avoid concomitant use
Severe Drug-Food Interactions	No known drug-food interactions at this time
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	SCr, CrCl
Used in Pediatric Areas	Safety and efficacy have not been established
Renal or Hepatic Dosing	Renal Dosing: • In NVAF, DVT, and PE: (CrCl 15 to 50 mL/min): 30 mg once daily • Limited use in patients with NVAF: Should not be used if patient has CrCl > 95 mL/min because of a demonstrated increase in the risk of ischemic stroke at 60 mg/dosing when compared to warfarin Hepatic Dosing: • Not recommended in moderate or severe impairment (Child-Pugh classes B and C)
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: • Active pathological bleeding Warnings and precautions: • Reduced efficacy in NVAF patients with CrCl >95 mL/min • Increased risk of stroke following abrupt discontinuation of therapy • Increased risk of bleeding • Risk of hematoma and paralysis with spinal/epidural anesthesia or puncture. Weigh the risks and benefits before neuraxial intervention in patients taking or planning to take edoxaban
Special administration technique or considerations	• Can be taken with or without food • Discontinue therapy 24 hours before surgery or other invasive procedures with a risk of bleeding
Prepared by	Andrew Erickson, PharmD Candidate 2015

Secukinumab Injection / Cosentyx / Novartis	
Generic Name / Brand Name / Company	Secukinumab injection / Cosentyx / Novartis
Date of approval	January 21, 2015
Drug Class (Mechanism of Action if novel agent)	Monoclonal antibody against cytokine IL-17A; selectively binds IL-17A to reduce inflammatory and immune responses.
Indication	Treatment of moderate to severe plaque psoriasis in adults who are eligible for systemic therapy or phototherapy
Comparative agent – Therapeutic interchange?	Ustekinumab
Dosage forms/strengths. Common Dose/sig	150 mg lyophilized powder in vial for reconstitution 150 mg/mL solution in Sensoready pen (autoinjector pen) 150 mg/mL solution in prefilled syringe

	Inject 300 mg (two 150 mg injections) subcutaneously once weekly for weeks 0, 1, 2, 3, and 4, then inject 300 mg once every 4 weeks. Rotate injection sites (upper arms, thighs, or any quadrant of abdomen).
DEA Schedule	Not applicable
Date of market availability	1st or 2nd quarter 2015
Similar Medications (Look-Alike Sound-Alike)	Cogentin, Cosyntropin
CLINICAL USE EVALUATION	
Common Adverse Effects	Nasopharyngitis, diarrhea, upper respiratory tract infection, rhinitis, oral herpes, pharyngitis, urticaria, and rhinorrhea commonly occurred in 1% or more study patients.
Severe Adverse Effects	Serious infections, exacerbations of Crohn's disease, and hypersensitivity reactions
Severe Drug-Drug Interactions	Do not administer live vaccines to patients treated with secukinumab. Non-live vaccines may not be effective if administered in patients treated with secukinumab. All appropriate vaccinations should be completed prior to initiating secukinumab. Secukinumab may increase CYP450 enzyme concentrations. Monitor the therapeutic effects of drugs that are CYP450 substrates when used concomitantly with secukinumab.
Severe Drug-Food Interactions	None reported
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Prior to treatment, test for tuberculosis. Monitor for infections and hypersensitivity reactions.
Used in Pediatric Areas	Not established
Renal or Hepatic Dosing	Not established
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Contraindicated in patients with prior hypersensitivity or anaphylactic reactions to secukinumab or other drug components. If serious allergic reaction occurs, immediately discontinue secukinumab. • Patients with latex allergy should not handle the removable cap of the Sensoready pen and prefilled syringe. • Secukinumab may increase risk of infection and exacerbation of Crohn's disease. • Do not administer drug in patients with active tuberculosis. All patients should be tested for tuberculosis prior to initiating secukinumab.
Special administration technique or considerations	• The single-use vial is only to be administered by a healthcare provider. Patients may use the Sensoready pen or prefilled syringe to self-administer secukinumab. • Prior to injection, remove secukinumab from the refrigerator and allow it to reach room temperature by waiting 15 to 30 minutes. Once removed from the refrigerator, secukinumab must be administered within 1 hour. • Check for particulates and discoloration prior to injection.
Prepared by	Anne Kim, PharmD, MPH, MIT

Carbidopa and Levodopa Enteral Suspension / Duopa / Abbvie	
Generic Name / Brand Name / Company	Carbidopa and levodopa enteral suspension / Duopa / Abbvie
Date of approval	January 13, 2015
Drug Class (Mechanism of Action if novel agent)	Aromatic amino acid decarboxylation inhibitor and aromatic amino acid
Indication	Treatment of motor fluctuations in patients with advanced Parkinson's disease
Comparative agent – Therapeutic interchange?	Monoamine oxidase B inhibitors, dopamine agonists, catechol-o-methyl transferase inhibitors

Dosage forms/strengths. Common Dose/sig	Enteral suspension: 4.63 mg carbidopa and 20 mg levodopa per mL in each cassette (cassette contains about 100 mL of enteral suspension) Administer a maximum daily dose of 2000 mg of levodopa (i.e., 1 cassette per day) over 16 hours with the CADD®-Legacy 1400 portable infusion pump through the percutaneous endoscopic gastrostomy with jejunal tube (PEG-J). Titrate dose to clinical response.
DEA Schedule	Not applicable
Date of market availability	2015
Similar Medications (Look-Alike Sound-Alike)	None
CLINICAL USE EVALUATION	
Common Adverse Effects	Complication of device insertion, nausea, constipation, dyskinesia, depression, peripheral edema, hypertension, upper respiratory tract infection, oropharyngeal pain, and incision site erythema
Severe Adverse Effects	See Critical Issues
Severe Drug-Drug Interactions	• Concomitant use with nonselective monoamine oxidase inhibitors is contraindicated (wash-out period of 2 weeks). Selective monoamine oxidase B inhibitors may be used concomitantly with carbidopa-levodopa, but monitor for orthostatic hypotension. • Concomitant use with antihypertensive drugs may increase risk of hypotension. • Concomitant use with isoniazid and dopamine D2 receptor antagonists (e.g., phenothiazines, risperidone, metoclopramide) may decrease efficacy of levodopa. Monitor patients for worsening Parkinson's symptoms.
Severe Drug-Food Interactions	• Iron salts (iron in multivitamins) chelate carbidopa and levodopa, which decreases the bioavailable dose. Monitor patients for worsening Parkinson's symptoms if concomitant use is required. • High-protein diet may decrease the bioavailable dose of levodopa.
Important Lab Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	None
Used in Pediatric Areas	Not established
Renal or Hepatic Dosing	Not reported
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Contraindicated in patients currently taking nonselective monoamine oxidase inhibitor (e.g., phenelzine and tranylcypromine) or have taken it within 2 weeks due to increased risk of hypertension. • By nature of the route of administration, complications including bezoar, ileus, implant site erosion/ulcer, intestinal hemorrhage, intestinal ischemia, intestinal obstruction, intestinal perforation, pancreatitis, peritonitis, pneumoperitoneum, and post-operative wound infections may occur. • Falling asleep during activities and sudden somnolence have been reported. Consider discontinuing if significantly disruptive to daily activities. • Enteral carbidopa-levodopa may increase risk of orthostatic hypotension, hallucinations/psychosis/confusion, impulsive/compulsive behaviors, depression/suicidality, dyskinesia, neuropathy, cardiovascular ischemic events and arrhythmias, melanoma, elevated BUN and CPK, and intraocular pressure.
Special administration technique or considerations	• Oral Parkinson's disease medications should be taken the morning of the PEG-J procedure. Use a 1:4 ratio to convert from oral immediate-release carbidopa-levodopa tablets. Titrate the daily dose based on the

	directions for morning and continuous dose adjustments found in the prescribing information. • Do not abruptly discontinue or rapidly decrease dose. Taper patients off or switch to oral-immediate-release carbidopa-levodopa tablets.
Prepared by	Anne Kim, PharmD, MPH, MIT

Meningococcal group B vaccine / Bexsero / Novartis	
Generic Name / Brand Name / Company	Meningococcal group B vaccine / Bexsero / Novartis
Date of approval	January 23, 2015
Drug Class (Mechanism of Action if novel agent)	Vaccine against *Neisseria meningitidis* serogroup B proteins NHBA, NadA, fHbp, and PorA.
Indication	Prophylaxis; for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B in subjects 10 to 25 years of age
Comparative agent – Therapeutic interchange?	Trumenba
Dosage forms/strengths. Common Dose/sig	0.5 mL suspension in prefilled syringe Administer two 0.5 mL doses intramuscularly each at least 1 month apart
DEA Schedule	Not applicable
Date of market availability	Not reported
Similar Medications (Look-Alike Sound-Alike)	Bexxar, Meningococcal group B vaccine (Trumenba)
CLINICAL USE EVALUATION	
Common Adverse Effects	Pain at the injection site (≥83%), myalgia (≥48%), erythema (≥45%), fatigue (≥35%), headache (≥33%), induration (≥28%), nausea (≥18%), and arthralgia (≥13%)
Severe Adverse Effects	Severe allergic reaction
Severe Drug-Drug Interactions	Concomitant administration with adolescent vaccines has not been established.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	None
Used in Pediatric Areas	Not established in children <10 years of age
Renal or Hepatic Dosing	Not reported
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with history of hypersensitivity/severe allergic reaction to meningococcal B vaccine or any component of the vaccine. Patients allergic to latex should avoid handling the natural rubber latex tip caps of prefilled syringes. Patients with altered immunocompetence may have reduced immune response to vaccine. There is risk of syncope after vaccine administration. Monitor for anaphylactic reaction and syncope at time of administration. Vaccine may not protect against all meningococcal serogroup B strains.
Special administration technique or considerations	Shake syringe vigorously to get homogenous white suspension. Do not use if there is evidence of particulates or discoloration. Inject intramuscularly into the deltoid muscle. Store refrigerated and protected from light.
Prepared by	Anne Kim, PharmD, MPH, MIT