Highlights of Medication-Related FDA Activities – 9/1/15 – 9/30/15

FDA Drug Safety Communications & Drug Information Updates:

Updated Warnings for Safe Preparation and Handling of Treanda (bendamustine HCl) Injection for IV Administration 9/4/15

Following a warning earlier this year that bendamustine injection solution, which contains N,N-dimethylacetamide, was not to be used with closed system transfer devices, adapters, and syringes containing polycarbonate or acrylonitrile-butadiene-styrene, specific devices were tested by the manufacturer and found to be compatible with bendamustine injection solution. A complete listing of compatible closed system transfer devices, syringes, vial adapters, and gloves can be found on the FDA web site: http://www.fda.gov/Drugs/DrugSafety/ucm437469.htm.

Compounded or Repackaged Drugs Stored in Becton-Dickinson Syringes: FDA Expands Warning - Alert now includes 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes 9/8/15

The FDA is extending its warning not to use compounded or repackaged drugs stored in Becton-Dickinson general purpose syringes unless there are no alternatives. The new warning added 1 ml, 10 ml, 20 ml, 30 ml, and BD oral syringes to the list. All of these syringes have rubber stopper material that may degrade drug potency over time. General-purpose syringes are approved only for fluid aspiration and injection, not as closed containers.

Invokana and Invokamet (canagliflozin): Drug Safety Communication – New Information on Bone Fracture Risk and Decreased Bone Mineral Density 9/10/15

The FDA has strengthened the WARNING AND PRECAUTION section and revised the ADVERSE REACTIONS section of the drug labels for Invokana and Invokamet to reflect new information regarding decreased bone mineral density and increased risk of fractures. The FDA is also continuing to investigate these issues with the other medications in the SGLT-2 class, including dapagliflozin (Farxiga, Xigduo XR) and empagliflozin (Jardiance, Glyxambi, Synjardy), for possible need of additional labeling changes. Patients should not stop taking these medications without first discussing the risks and benefits with their health care provider. Health care providers and patients should report side effects of SGLT-2 medications to the FDA MedWatch program.

Clozapine: Drug Safety Communication – Modified Monitoring and New Shared REMS Program 9/15/15

The FDA has revised the requirements for monitoring, prescribing, dispensing, and receiving clozapine. The prescribing information has been revised to more clearly explain how to monitor patients for neutropenia and manage clozapine treatment. New monitoring requirements will assess neutropenia using the absolute neutrophil count (ANC) only, rather than in conjunction with the white blood cell count, and will permit continued clozapine treatment with a lower ANC. In addition, a new shared REMS program has been approved, the Clozapine REMS Program, to reduce confusion associated with having separate registries for individual clozapine products. Patients currently treated with clozapine will be automatically transferred to the new program. Starting October 12, 2015, prescribers and pharmacies will be required to be certified in the Clozapine REMS Program to prescribe and dispense clozapine.

Tramadol: Drug Safety Communication – FDA Evaluating Risks of Using in Children Aged 17 and Younger 9/21/2015

The FDA is investigating the use of tramadol in children aged 17 and younger. This is due to a risk of slowed or difficult breathing. Currently, tramadol is not FDA-approved for use in children. Data has shown that it has been used in off-label instances in the pediatric population. Parents and caregivers of children who notice signs of slowed or difficult breathing, confusion, or unusual sleepiness should stop tramadol and seek medical attention immediately.

Avycaz (ceftazidime and avibactam): Drug Safety Communication – Dose Confusion and Medication Errors 9/22/2015

The FDA is warning health care professionals about the risk of dosing errors with the antibacterial drug Avycaz. The label for Avycaz displays the strengths for the two different active ingredients, but the product is dosed based on the sum of the two active ingredients. The FDA revised the label to show the sum of the active ingredients is 2.5 grams.

Major Medication/Delivery Device Recalls Announced Through MedWatch:

Medistat Rx Sterile Products: Recall due to Possible Contamination 9/10/2015

Medistat Rx LLC is voluntarily recalling all of its non-expired sterile compounded products due to possible contamination. The sterility of products came into question after FDA and Alabama State inspectors found deficiencies, following reports of adverse events possibly connected with these products. Products affected were distributed nationwide between November 1, 2014 and September 3, 2015. Healthcare providers should pull and quarantine possibly affected products.

FDA Issues Consumer Advice: Shree Baidyanath Brand Ayurvedic Dietary Supplements 9/18/15

The FDA issued a warning that the following Shree Baidyanath Brand Ayurvedic Dietary Supplements have been found to contain high levels of lead and/or mercury: Agnitundi Bati, Arodyavardhini Bati, Brahmi Bati, Chitrakadi Bati, Gaisantak Bati, Marichyadi Bati, Rajahpravartini Bati, Saptamrit Lauh, Sarivadi Bati and Shankh Bati. Patients should be instructed to immediately stop using these products and consult their health care provider for screening and possible testing. At least one retailer has recalled the products.

US Compounding, Inc: Voluntary Recall of All Sterile Compound Products 9/24/15

US Compounding is voluntarily recalling all lots of sterile products aseptically compounded and packaged by US Compounding because of the lack of sterility assurance for the products. Products were distributed nationwide to patients, providers, hospitals, or clinics between 3/14/15 and 9/9/15.

Dietary Supplement Recalls & Public Notifications

In September, 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)***
Meizi Super Power Fruits Herbal Slimming Formula	Weight loss	Sibutramine
Miracle Diet 30*	Weight loss	Phenolphthalein
Miracle Rock 48*	Sexual function	Thiosildenafil
Lucy's Weight Loss System Pink Bikini and Shorts on the Beach Blue and Gold Edition*	Weight Loss	Sibutramine, phenolphthalein
Rhino 7*	Sexual function	Desmetheyl carbondenafil, dapoxetine

*Recalled

New Product Shortages Reported by the FDA:	***Date Initially Posted***
Metoprolol injection	9/9/15
Thiotepa for injection (Thoplex)	9/15/15
Mometasone furoate monohydrate (Nasonex)	9/21/15

Product Discontinuations/Withdrawals	***Date Posted***
Hexabrix (Ioxaglate meglumine/ioxaglate sodium, Guerbet LLC) - Medical imaging product discontinued for business reasons; no other products with same composition available.	9/18/15
Iodopen (sodium iodide 1000 mcg/10 mL injection, Fresenius Kabi USA LLC) – Trace element for use in total parenteral nutrition discontinued for business reasons; no single ingredient sodium iodide product remains available.	9/18/15
Sodium acetate injection USP 32.8% Concentrated, Fresenius Kabi USA LLC – Discontinued for business reasons; product remains available from other manufacturers.	9/18/15
Rebetol (Ribavirin USP capsules, Merck) – Discontinued for business reasons; ribavirin capsules remain available from other manufacturers.	9/23/15
PegIntron (peginterferon alfa-2b, Merck) – Vials discontinued; prefilled syringes previously discontinued. Supplies estimated to be depleted by February 2016.	9/24/15
Scopolamine hydrobromide Injection, USP 0.4 mg/mL, Fresenius Kabi USA, LLC – Discontinued for business reasons; injectable scopolamine is not available from other manufacturers.	9/28/15

New Drug Approvals:	***Description***	***Date Approved***
Rolapitant / Varubi / Tesaro Inc.	See attached drug summary	9/2/15
Uridine triacetate / Xuriden / Wellstat Therapeutics	See attached drug summary	9/4/15
Cariprazine / Vraylar / Forest Labs LLC	See attached drug summary	9/17/15
Trifluridine-Tipiracil / Lonsurf / Taiho Oncology	See attached drug summary	9/22/15
Insulin Degludec / Tresiba / Novo Nordisk	See attached drug summary	9/25/15
Insulin Degludec-Insulin Aspart / Ryzodeg 70/30 /Novo Nordisk	See attached drug summary	9/25/15

New Indications:	***Description***	***Date Approved***
Mesalamine / Delzicol / Warner Chilcott	Indication expanded to include use in pediatric patients 5 years of age and older with mildly to moderately active ulcerative colitis	9/9/15
Adalimumab / Humira / AbbVie	Treatment of moderate to severe hidradenitis suppurativa	9/9/15
Tiotropium bromide / Spiriva Respimat / Boehringer Ingelheim	Maintenance treatment of asthma in patients 12 years of age and older at dose of 2.5 mcg once daily (delivered as two 1.25 mcg puffs)	9/16/15

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Ticagrelor / Brilinta / AstraZeneca	New 60 mg dose twice daily approved for secondary prevention beyond the first year after myocardial infarction	9/3/15
Aspirin Extended Release Capsules / Durlaza / New Haven Pharma	162.5 mg aspirin extended release capsule for secondary prevention of stroke and acute cardiovascular events	9/4/15
Fluorouracil 4% cream / Tolak / Hill Dermac	New 4% cream for the topical treatment of actinic keratosis of the face, ears, and scalp	9/18/15

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Rolapitant / Varubi / Tesaro Inc.	
Generic Name / Brand Name / Company	Rolapitant / Varubi / Tesaro Inc.
Date of approval	9/2/15
Drug Class (Mechanism of Action if novel agent)	Substance P/neurokinin 1 (NK1) receptor antagonist
Indication	Prevention of delayed nausea and vomiting associated with initial and repeated courses of emetogenic cancer chemotherapy, including but not limited to, highly emetogenic chemotherapy
Comparative agent – Therapeutic interchange?	Aprepitant, netupitant
Dosage forms/strengths. Common Dose/sig	Tablet: 90 mg Dose: 180 mg (2 tablets) by mouth 1 to 2 hours prior to chemotherapy
DEA Schedule	Not applicable
Date of market availability	Q4 of 2015
Similar Medications (Look-Alike Sound-Alike)	None
CLINICAL USE EVALUATION	
Common Adverse Effects	Neutropenia, hiccups, abdominal pain, decreased appetite, dizziness, dyspepsia, urinary tract infection, stomatitis, anemia
Severe Adverse Effects	Altered heart rhythms
Severe Drug-Drug Interactions	• Moderate CYP2D6 inhibitor with inhibitory effects lasting at least 7 days, so may require dose adjustments of CYP2D6 substrates o Contraindicated with thioridazine, a CYP2D6 substrate o Avoid use with pimozide; QT prolongation risk if concomitant use • Inhibitor of Breast-Cancer-Resistance Protein (BCRP), use lowest effective dose when taking rosuvastatin concomitantly • Inhibitor of P-glycoprotein, monitor adverse effects with narrow therapeutic index medications such as digoxin • Strong CYP3A4 inducers significantly reduce plasma concentrations of rolapitant, decreasing efficacy
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	None
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	No dose adjustment in mild or moderate hepatic impairment (Child-Pugh class A or B) or renal impairment. Avoid use in severe hepatic impairment (Child-Pugh class C). Has not been assessed in severe renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Rolapitant is a moderate CYP2D6 inhibitor, contraindicated with thioridazine, a CYP2D6 substrate • Avoid use, or use with caution, with other CYP2D6 substrates with narrow therapeutic index
Special administration technique or considerations	• Administer in conjunction with dexamethasone and a 5-hydroxytryptamine-3 receptor antagonist • Administer rolapitant 1 to 2 hours prior to initiation of each chemotherapy cycle, but at no less than 2-week intervals
Prepared by	Renee Saxon, Pharm.D. Candidate 2016

Uridine triacetate / Xuriden / Wellstat Therapeutics Corporation	
Generic Name / Brand Name / Company	Uridine triacetate / Xuriden / Wellstat Therapeutics Corporation
Date of approval	9/4/15
Drug Class (Mechanism of Action if novel agent)	Uridine triacetate is a prodrug that is deacetylated by non-specific esterases throughout the body to uridine, the active component.
Indication	Uridine replacement in hereditary orotic aciduria (patients with genetic uridine deficiency)
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Oral granules: 2 grams orange-flavored oral granules (95% w/w) in single-use packets Starting dose: 60 mg/kg by mouth once daily Increase the dose to 120 mg/kg (not to exceed 8 grams) by mouth once daily for insufficient efficacy
DEA Schedule	None
Date of market availability	Early 2016
Similar Medications (Look-Alike Sound-Alike)	None
CLINICAL USE EVALUATION	
Common Adverse Effects	None known
Severe Adverse Effects	None known
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. (Need Pop Up?)	Increase dose for insufficient efficacy as indicated by: -Levels of orotic acid in urine above normal or increased above expected -Red blood cell or white blood cell indices showing evidence of worsening -Worsening of other signs or symptoms of disease
Used in Pediatric Areas	May be used in pediatric patients
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Maximum daily dose: 8 grams
Special administration technique or considerations	• Measure dose using scale accurate to at least 0.1 g or a graduated teaspoon accurate to the fraction of the dose to be administered. • Once a measured dose has been removed from the packet, discard the unused portion of granules. Do not use any granules left in the open packet. • Administration with food: Place in 3 to 4 ounces of applesauce, pudding or yogurt and mix. Swallow immediately. Do not chew the granules. Do not save the applesauce/pudding/yogurt for later use. Drink at least 4 ounces of water. • Administration in milk or infant formula: Following recommendations in product labeling to mix weighed dose with 5 mL milk or infant formula in an oral syringe. Administered using an oral syringe in the patient's mouth between the cheek and gum at the back of the mouth. Gently push the plunger. Refill the syringe with another 5 mL of milk/infant formula, and gently swirl to resuspend remaining granules. Administer using the above technique.
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Cariprazine / Vraylar / Forest Labs LLC	
Generic Name / Brand Name / Company	Cariprazine / Vraylar / Forest Labs LLC
Date of approval	9/17/15
Drug Class (Mechanism of Action if novel agent)	Cariprazine is an atypical antipsychotic
Indication	Treatment of schizophrenia and acute treatment of manic or mixed episodes associated with bipolar I disorder.
Comparative agent – Therapeutic interchange?	Aripiprazole, asenapine, brexpiprazole, clozapine, iloperidone, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone
Dosage forms/strengths. Common Dose/sig	Capsules: 1.5 mg, 3 mg, 4.5 mg and 6 mg Schizophrenia: starting dose 1.5 mg/day, recommended dose 1.5 mg to 6 mg/day Bipolar Mania: starting dose 1.5 mg/day, recommended dose 3 mg to 6 mg/day
DEA Schedule	None
Date of market availability	First quarter 2016
Similar Medications (Look-Alike Sound-Alike)	Carbamazepine
CLINICAL USE EVALUATION	
Common Adverse Effects	Schizophrenia: extrapyramidal symptoms and akathisia Bipolar Mania: extrapyramidal symptoms, akathisia, dyspepsia, vomiting, somnolence, and restlessness
Severe Adverse Effects	May cause withdrawal symptoms in neonates with third trimester exposure or extrapyramidal symptoms in all ages.
Severe Drug-Drug Interactions	• Strong CYP3A4 inhibitors: reduce cariprazine dosage by half • CYP3A4 inducers: avoid use with cariprazine
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Blood glucose and lipids; CBC if pre-existing low WBC or history of drug-induced leukopenia/neutropenia
Used in Pediatric Areas	Safety and efficacy has not been established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustment is required in patients with mild to moderate hepatic impairment (Child-Pugh score between 5 and 9) or mild to moderate renal impairment (CrCL $\geq$ 30 mL/min). Use is not recommended in patients with severe hepatic impairment (Child-Pugh score between 10 and 15) or severe renal impairment (CrCL < 30 mL/min)
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: known hypersensitivity to product Warnings: • Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack) in elderly patients with dementia-related psychosis; not indicated for the treatment of patients with dementia-related psychosis. • The half-life of the active metabolite 1 to 3 weeks; monitor for adverse reactions and patient response for several weeks after starting cariprazine and with each dose change. • Neuroleptic malignant syndrome • Tardive dyskinesia • Monitor for metabolic changes • Orthostatic hypotension: Monitor heart rate and blood pressure.
Special administration technique or considerations	• The dosage can be increased to 3 mg on Day 2 • Depending upon clinical response and tolerability, further dose adjustments can be made in 1.5 mg or 3 mg increments.
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Trifluridine & Tipiracil / Lonsurf/ Taiho Oncology	
Generic Name / Brand Name / Company	Trifluridine & Tipiracil / Lonsurf/ Taiho Oncology
Date of approval	9/22/15
Drug Class (Mechanism of Action if novel agent)	Combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor.
Indication	Treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.
Comparative agent – Therapeutic interchange?	Not applicable
Dosage forms/strengths. Common Dose/sig	• Tablets: 15 mg trifluridine/6.14 mg tipiracil; 20 mg trifluridine/8.19 mg tipiracil • Recommended dose: 35 mg/m^2/dose (based on the trifluridine component) orally twice daily on Days 1 through 5 and Days 8 through 12 of each 28-day cycle.
DEA Schedule	None
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	Trifluridine ophthalmic
CLINICAL USE EVALUATION	
Common Adverse Effects	The most common adverse reaction ($\geq$ 10%) are anemia, neutropenia, asthenia/fatigue, nausea, thrombocytopenia, decreased appetite, diarrhea, vomiting, abdominal pain, and pyrexia.
Severe Adverse Effects	Severe myelosuppression.
Severe Drug-Drug Interactions	No pharmacokinetic drug-drug interaction studies have been conducted
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Obtain complete blood cell counts prior to and on Day 15 of each cycle
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	No dose adjustment is recommended at this time for patients with mild hepatic impairment or mild/moderate renal impairment, however patients with moderate renal impairment may require dose modification for increased toxicity.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Severe Myelosuppression: Obtain complete blood counts prior to and on Day 15 of each cycle. Reduce dose and/or hold therapy as clinically indicated. • Embryo-Fetal Toxicity: Fetal harm can occur. Advise women of potential risk to a fetus.
Special administration technique or considerations	• Maximum 80 mg per dose based on the trifluridine component. • Administer twice daily within one hour of completion of morning and evening meals. • Round dose to the nearest 5 mg increment • Trifluridine/tipiracil is a cytotoxic drug. Follow applicable special handling and disposal procedures. • Do not initiate the 28-day cycle until: ANC is $\geq$ 1,500/mm^3 or febrile neutropenia is resolved, platelets are $\geq$ 75,000/mm^3, and Grade 3 or 4 non-hematological adverse reactions are resolved to Grade 0 or 1 • Within a treatment cycle, withhold therapy if: ANC < 500/mm^3 or febrile neutropenia, platelets less than 50,000/mm^3, or Grade 3 or 4 non-hematological adverse reactions.
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Insulin Degludec / Tresiba / Novo Nordisk	
Generic Name / Brand Name / Company	Insulin Degludec/Tresiba/Novo Nordisk
Date of approval	9/25/15
Drug Class (Mechanism of Action if novel agent)	Long-acting basal human insulin analog
Indication	To improve glycemic control in adults with diabetes mellitus
Comparative agent – Therapeutic interchange?	Insulin detemir, insulin glargine
Dosage forms/strengths. Common Dose/sig	Tresiba 100 units/mL (U-100): 3 mL FlexTouch disposable prefilled pen Tresiba 200 units/mL (U-200): 3 mL FlexTouch disposable prefilled pen • Naïve Type 1 Diabetes Mellitus: 1/3 to 1/2 of the total daily insulin dose. The remainder of the total daily insulin dose should be administered as a short acting insulin and divided between each daily meal • Naïve Type 2 Diabetes Mellitus: 10 units subcutaneously once daily • Type 1 and Type 2 Diabetes Mellitus: Start at same unit dose as the total daily long or intermediate-acting insulin dose
DEA Schedule	None
Date of market availability	First quarter 2016
Similar Medications (Look-Alike Sound-Alike)	Insulin detemir
CLINICAL USE EVALUATION	
Common Adverse Effects	Hyperglycemia or hypoglycemia with changes in insulin regimen, irritation at the injection site, allergic reactions, lipodystrophy, pruritus, rash, edema, weight gain
Severe Adverse Effects	Hypoglycemia, hypersensitivity, hypokalemia, edema
Severe Drug-Drug Interactions	Fluid retention and heart failure with concomitant thiazolidinediones
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Blood glucose and HbA1c; potassium levels in patients at risk for hypokalemia
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dose adjustment. Monitor on an individual basis in patients with renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Do not use for the treatment of diabetic ketoacidosis • Contraindicated during episodes of hypoglycemia or patients with a hypersensitivity to the product or product ingredients • Hypoglycemia • Hypokalemia
Special administration technique or considerations	• Visually inspect for particulate matter and discoloration. Only use if solution is clear and colorless • Inject into the thigh, upper arm, or abdomen • Rotate the injection site so as to prevent lipodystrophy • Do not dilute or mix with any other insulin products or solutions • Do not transfer from pen into a syringe for administration • Inject once daily at any time of the day • Recommended days between dose increase is 3 to 4 days • Inject during waking hours upon discovering a missed dose. Make sure that at least 8 hours have elapsed between consecutive injections
Prepared by	Renee Saxon, Pharm.D. Candidate 2016

Insulin Degludec & Insulin Aspart / Ryzodeg 70/30 /Novo Nordisk	
Generic Name / Brand Name / Company	Insulin Degludec & Insulin Aspart /Ryzodeg 70/30 / Novo Nordisk
Date of approval	9/25/15
Drug Class (Mechanism of Action if novel agent)	Long acting and short acting insulin
Indication	To improve glycemic control in adults with diabetes mellitus
Comparative agent – Therapeutic interchange?	Basal/bolus regimen; NPH/regular 70/30 mix
Dosage forms/strengths. Common Dose/sig	Ryzodeg 70/30 100 units/mL (U-100): 3 mL FlexTouch disposable prefilled pen • Inject subcutaneously once or twice daily with any main meal. Administer a rapid or short-acting insulin at other meals if needed • Naïve Type 1 Diabetes Mellitus: 1/3 to 1/2 of the total daily insulin dose. The remainder of the total daily insulin dose should be administered as a short acting insulin and divided between each daily meal • Naïve Type 2 Diabetes Mellitus: 10 units subcutaneously once daily
DEA Schedule	None
Date of market availability	First quarter 2016
Similar Medications (Look-Alike Sound-Alike)	None
CLINICAL USE EVALUATION	
Common Adverse Effects	Hyperglycemia or hypoglycemia with changes in insulin regimen, irritation at the injection site, allergic reactions, lipodystrophy, pruritus, rash, edema, weight gain
Severe Adverse Effects	Hypoglycemia, hypersensitivity, hypokalemia, edema
Severe Drug-Drug Interactions	Fluid retention and heart failure with concomitant thiazolidinediones
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Blood glucose and HbA1c; potassium levels in patients at risk for hypokalemia
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dose adjustment. Monitor on an individual basis in patients with renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Do not use for the treatment of diabetic ketoacidosis • Contraindicated during episodes of hypoglycemia or patients with a hypersensitivity to product or any product ingredients • Hypoglycemia • Hypokalemia
Special administration technique or considerations	• Visually inspect for particulate matter and discoloration. Only use if solution appears clear and colorless • Inject subcutaneously into the thigh, upper arm, or abdomen • Rotate injection site to reduce risk of lipodystrophy • Recommended time between dose increases is 3 to 4 days • If a dose is missed, the next dose should be taken with the next main meal of that day and thereafter resume usual dosing schedule
Prepared by	Renee Saxon, Pharm.D. Candidate 2016