Highlights of FDA Activities – 6/1/18 – 6/30/18

FDA Drug Safety Communications & Drug Information Updates:

Compounded Products Containing Triamcinolone-Moxifloxacin by Guardian Pharmacy Services: MedWatch Alert – Adverse Events 6/14/18

At least 43 patients reported adverse events after receiving eye injections of Guardian's Pharmacy Services compounded triamcinolone-moxifloxacin product during cataract surgery. The FDA identified multiple substances in the product, including amounts of poloxamer 407 exceeding the maximum amount of poloxamers in FDA-approved ophthalmic products, and found that autoclaving and sonication caused the poloxamer 407 to degrade. The FDA advised compounding pharmacies to determine, based on the route of administration and the organ or tissue involved, whether excipients are safe in the amount that will be present in an administered dose.

Pembrolizumab and Atezolizumab Efficacy Prompt Restricted Indication: Drug Information Update 6/20/18

The FDA is restricting the indications for pembrolizumab (Keytruda) and atezolizumab (Tecentriq) to use in patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing therapy. This revision in the approved indication resulted from study results showing decreased survival associated with the use of pembrolizumab or atezolizumab as monotherapy compared to platinum-based chemotherapy in patients with metastatic urothelial cancer who have not received prior therapy and who have low expression of the protein programmed death ligand 1 (PD-L1). The labels of both drugs have been revised to reflect the restricted indications.

Monsel's Solution (ferric subsulfate 20%) by MedGyn Products: Possible Contamination or Decreased Quality 6/29/18

The FDA advised health care professionals not to use any Monsel's Solution (ferric subsulfate 20%) manufactured by BioDiagnostics International, Brea, California, and distributed by MedGyn Products, Inc., Addison, Illinois, because the drug product was made under poor conditions. The solution is sold in a carton containing 12 single application vials and 12 applicators, 8 mL each, NDC 42721-112-08. Health care professionals should immediately check their medical supplies, quarantine any of MedGyn's Monsel's Solution, and not administer it to patients.

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

Naloxone Injection, Carpuject Single-use Cartridge Syringe System by Hospira: Recall – Particulate Matter 6/4/18

Hospira recalled lots 72680LL and 76510LL of Naloxone Hydrochloride Injection, USP, 0.4 mg/mL, 1 mL in 2.5 mL, Carpuject Single-use Cartridge Syringe System (NDC 0409-1782-69), to the hospital/institution level due to the potential presence of embedded and loose particulate matter on the syringe plunger.

Neostigmine Methylsulfate 1 mg/mL, 5 mg per 5 mL and Neostigmine Methylsulfate 1 mg/mL, 3 mg per 3 mL, in a 5 mL syringe: Recall – Mislabeled 6/29/18

Fagron Sterile Services recalled two lots of Neostigmine Methylsulfate 5 mL syringes to the user/hospital/clinic level (Lots C274-000004690 &C74-000004678). The specified product lots were recalled following a confirmed customer complaint that some syringe units containing Neostigmine Methylsulfate 1 mg/mL, 5 mg per 5 mL are incorrectly labelled as Neostigmine Methylsulfate 1 mg/mL, 3 mg per 3 mL. Secondary packages are properly labelled as Neostigmine Methylsulfate 1 mg/mL, 5 mg per 5 mL.

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*
Kratom Powder Products by Gaia Ethnobotanical, Lot No.: 0102031800*	Pain relief, sedation	Salmonella
Kratom + CBD, CBD infused Maeng Da capsules by Blisssful Remedies, Lot No. 112710*	Pain relief, sedation	Salmonella
Kratom, Gold Series Ultra Enhanced Indo (100% Mitragyna speciose) capsules by Blisssful Remedies, Lot No. 112710*	Pain relief, sedation	Salmonella
Kratom, Red Maeng Da (100% Mitragyna speciose) capsules by Blisssful Remedies, Lot No. 112710*	Pain relief, sedation	Salmonella
PAYA Dietary Supplement Product	Weight loss	Sibutramine[1]
Prescript-Assist Dietary Supplement by LL's Magnetic Clay Inc, lots 1356300 (exp. 01/2019), 1405700 (exp. 03/2019), 17A128 (exp. 03/2021), and W00103 (exp. 06/2019)*	Prebiotic, probiotic	Undeclared allergens, including almonds, crustaceans, dairy, casein, eggs, and peanuts

*Recalled

[1]Sibutramine has been associated with increased cardiovascular events; discontinued 2010[FDA]

New Product Shortages

Date Initially Posted

No new shortages were reported by the FDA in June

Product Discontinuations/Withdrawals	*Date Posted*
Aripiprazole tablets (Teva): remains available from other generic manufacturers	6/5/18
Clonazepam tablets (Sandoz): remains available from other generic manufacturers	6/5/18
Hydrocodone Bitartrate and Homatropine Methylbromide Oral Solution (Perrigo): remains available from other generic manufacturers	6/5/18
Terazosin HCl capsules (Sandoz): remains available from other generic manufacturers	6/5/18
Terazosin HCl capsules (Mylan): remains available from other generic manufacturers	6/19/18
Divalproex Sodium Delayed Release tabs (Teva): remains available from other generic manufacturers	6/11/18
Gemcitabine HCl (Gemzar) Lyophilized Powder for Injection (Eli Lilly): remains available from generic manufacturers.	6/11/18
Lamotrigine chewable/dispersible tablets (Teva): remains available from other generic manufacturers	6/12/18
Ketoprofen Capsules (Teva): remains available from other generic manufacturers	6/13/18
Mometasone Furoate (Elocon) 0.1% Ointment (Merck): remains available from generic manufacturers	6/13/18
Norethindrone/ethinyl estradiol (Ortho Novum 7/7/7) (Janssen) remains available from generic manufacturers	6/20/18
Norethindrone/ethinyl estradiol (Necon 7/7/7) (Actavis): remains available from other generic manufacturers	6/20/18
Norethindrone (Ortho Micronor) (Janssen): remains available from generic manufacturers	6/20/18
Olmesartan Medoxomil and Hydrochlorothiazide (Teva): remains available from other generic manufacturers	6/21/18
Meperidine HCl Injection (ICU Medical, Inc.): remains available from other generic manufacturers	6/25/18
Telmisartan Tablets (Teva): remains available from other generic manufacturers	6/28/18

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Moxidectin / Medicines Development for Global Health	Treatment of onchocerciasis (river blindness) due to *Onchocerca volvulus* in patients aged 12 years and older.	6/13/18
Plazomicin / Zemdri / Achaogen, Inc.	Treatment of patients 18 years of age or older with Complicated Urinary Tract Infections (cUTI) including Pyelonephritis	6/25/18
Cannabidiol / Epidiolex / GW Research Ltd	Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older	6/25/18
Encorafenib / Braftovi / Array Biopharma Inc	In combination with binimetinib for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation	6/27/18
Binimetinib / Mektovi / Array Biopharma Inc	In combination with encorafenib for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation	6/27/18
Glycopyrronium / Qbrexza / Dermira	2.4% pre-moistened single-use cloths in 30-count pouches for the topical treatment of primary axillary hyperhidrosis (see attached drug summary)	6/29/18

New Indications:	***Description***	***Date Approved***
Pemetrexed disodium / Alimta / Eli Lilly & Co.	Use in combination with pembrolizumab and carboplatin for the first-line treatment of metastatic, non-squamous, non-small cell lung cancer	6/4/18
Methoxy polyethyleneglycol-epoeitin beta / Mircera / Vifor International	IV administration for treatment of anemia associated with chronic kidney disease in pediatric patients 5 to 17 years of age on hemodialysis who are converting from another erythropoiesis-stimulating agent after hemoglobin stabilization	6/7/18
Rituximab / Rituxan / Genentech	Treatment of adults with moderate to severe pemphigus vulgaris	6/7/18
Venetoclax / Venclexta / AbbVie	Treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma, with or without 17p deletion, who have received at least one prior therapy	6/8/18
Pembrolizumab / Keytruda/ Merck& Co.	Metastatic or recurrent PD-L1(+) cervical cancer with disease progression on or after chemotherapy	6/12/18
Bevacizumab / Avastin / Genentech	Use in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection	6/13/18
C1 esterase inhibitor [human] / Cinryze / Shire	Indication expanded to include routine prophylaxis against angioedema attacks in patients 6-11 years old	6/20/18
Pasireotide / Signifor LAR / Novartis	Treatment of adults with Cushing's disease for whom pituitary surgery is not an option or has not been curative	6/29/18

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Pegfilgrastim-jmdb / Fulphila / Mylan	Biosimilar to Neulasta to decrease the chance of infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.	6/4/18
Doxycycline hyclate tablets 100 mg / LymePak / Chartwell Pharma	Treatment of early Lyme disease in adults and pediatric patients 8 years of age and older weighing 45 kg or more	6/15/18
Albumin, human-kjda 5% and 25% / Albuminex 5% and 25% / Bio Products Laboratory	Human albumin 5% solution in 250 mL and 500 mL glass vials and 25% solution in 100 mL glass vials indicated for hypovolemia, ascites, hypoalbuminemia including from burns, acute nephrosis, acute respiratory distress syndrome, and cardiopulmonary bypass	6/19/18
Dehydrated alcohol / Ablysinol / Belcher Pharmaceuticals	1 mL and 5 mL injection for use to induce controlled cardiac septal infarction to improve exercise capacity in adults with symptomatic hypertrophic obstructive cardiomyopathy who are not candidates for surgical myectomy	6/21/18
Desmopressin acetate sublingual tablets / Nocdurna / Ferring	Sublingual tablets for treatment of nocturnal polyuria in adults who awaken at least 2 times per night to void	6/21/18
Pimavanserin / Nuplazid / Acadia Pharmaceuticals	34 mg capsule formulation and 10 mg tablet	6/28/18

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Moxidectin / Medicines Development for Global Health	
Generic Name / Brand Name / Company	Moxidectin / Medicines Development for Global Health
Date of approval	6/13/18
Drug Class (Mechanism of Action if novel agent)	Anthelmintic, macrocyclic lactone; inhibits intra-uterine embryogenesis and release of microfilariae from the adult worms, reduces motility of all stages and fertility of adult worms.
Indication	For the treatment of onchocerciasis (river blindness) due to *Onchocerca volvulus* in patients aged 12 years and older.
Comparative agent – Therapeutic interchange?	Ivermectin
Dosage forms/strengths. Common Dose/sig	Tablets: 2 m Dose: 8 mg (four 2 mg tablets) as a single oral dose.
DEA Schedule	Not applicable
Date of market availability	Unknown
Similar Medication Names	Ivermectin, moxifloxacin
Clinical Use Evaluation	
Common Adverse Effects	>10%: eosinophilia, pruritus, musculoskeletal pain, headache, lymphopenia, tachycardia, rash, abdominal pain, hypotension, pyrexia, leukocytosis, influenza-like illness, neutropenia, cough, lymph node pain, dizziness, diarrhea, hyponatremia and peripheral swelling.
Severe Adverse Effects	Mazzotti Reaction, symptomatic orthostatic hypotension, encephalopathy in *Loa loa* co-infected patients, edema, and worsening of onchodermatitis.
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.	None
Used in Pediatric Areas	Safe and effective in pediatric patients 12 years of age and older.
Renal or Hepatic Dosing	No dosage adjustment is mild to moderate renal impairment. Safety is unknown in severe renal impairment or end-stage renal disease.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Does not kill adult *O. volvulus*; follow-up is advised. The safety and efficacy of repeat administration of moxidectin in patients with *O. volvulus* has not been studied. Symptomatic treatments for orthostatic hypotension have included oral hydration, recumbency, intravenous normal saline, and/or parenteral corticosteroids. Mild to moderate cases of Mazzotti reaction (an inflammatory and allergic response to the death of microfilariae) have been treated with antihistamines and/or analgesics.
Special administration technique or considerations	Take orally with or without food
Prepared by	Amanda Cutler
Source	Moxidectin [prescribing information]. Melbourne, Australia: Medicines Development for Global Health, June 2018.

Plazomicin / Zemdri / Achaogen Inc	
Generic Name / Brand Name / Company	Plazomicin / Zemdri / Achaogen Inc
Date of approval	6/25/18
Drug Class (Mechanism of Action if novel agent)	Aminoglycoside antibacterial (acts by binding to bacterial 30S ribosomal subunit, thereby inhibiting protein synthesis); demonstrates concentration-dependent bactericidal activity.
Indication	Treatment of patients 18 years of age or older with complicated urinary tract infections, including pyelonephritis, caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Enterobacter cloacae*.
Comparative agent – Therapeutic interchange?	Reserve use for patients with limited or no alternative treatment options
Dosage forms/strengths. Common Dose/sig	Injection: 500 mg/10 mL (50 mg/mL) in a single-dose vial containing plazomicin sulfate equivalent to 500 mg plazomicin freebase. The recommended initial dosage is 15 mg/kg IV every 24 hours for patients with creatinine clearance at least 90 mL/min.
DEA Schedule	Not applicable
Date of market availability	July 2018
Similar Medication Names	Clindamycin, clarithromycin, azithromycin, erythromycin, gentamicin, streptomycin, tobramycin, vancomycin, daptomycin
Clinical Use Evaluation	
Common Adverse Effects	>1%: decreased renal function, diarrhea, hypertension, headache, nausea, vomiting and hypotension.
Severe Adverse Effects	Nephrotoxicity, ototoxicity, neuromuscular blockade, and fetal harm.
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.	Assess creatinine clearance in all patients prior to initiating therapy and daily during therapy.
Used in Pediatric Areas	Safety and effectiveness has not been established.
Renal or Hepatic Dosing	For patients with an estimated CLcr greater than or equal to 60 to less than 90 mL/min, recommended dose is 15 mg/kg every 24 hours. If estimated CLcr is greater than or equal to 30 to less than 60 mL/min, recommended dose is 10 mg/kg every 24 hours. If estimated CLcr is greater than or equal to 15 to less than 30 mL/min the recommended dose is 10 mg/kg every 48 hours. Trough plasma concentrations should be less than 3 mcg/mL.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with known hypersensitivity to any aminoglycoside. Warnings for nephrotoxicity, ototoxicity, neuromuscular blockade, fetal harm, hypersensitivity reactions, and *Clostridium difficile*-associated diarrhea.
Special administration technique or considerations	Administer by IV infusion over 30 minutes. After dilution, solution for administration is stable for 24 hours at room temperature at concentrations of 2.5 mg/mL to 45 mg/mL in both 0.9% Sodium Chloride Injection and Lactated Ringer's Injection. Compatibility with other drugs has not been established. Plazomicin should not be mixed with other drugs or physically added to solutions containing other drugs; other medications should not be infused simultaneously with plazomicin through the same IV line.
Prepared by	Hannah Sanchez, Sunao Tamukai
Source	Zemdri (plazomicin) [prescribing information]. South San Francisco, CA: Achaogen, Inc, June 2018.

Cannabidiol / Epidiolex / GW Research LTD	
Generic Name / Brand Name / Company	Cannabidiol / Epidiolex / GW Research LTD
Date of approval	6/25/18
Drug Class (Mechanism of Action if novel agent)	Cannabinoid; mechanism of anticonvulsant activity is unknown
Indication	For the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Oral solution: 100 mg/mL. The starting dose is 2.5 mg/kg twice daily (5 mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day), and then may be increased in weekly increments of 2.5 mg/kg twice daily to a maximum maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day).
DEA Schedule	Review Pending
Date of market availability	Pending DEA decision regarding controlled substance scheduling
Similar Medication Names	Dronabinol
Clinical Use Evaluation	
Common Adverse Effects	>10%: somnolence, decreased appetite, diarrhea, transaminase elevations, fatigue, malaise, asthenia, rash, insomnia, sleep disorder, poor quality sleep, and infections.
Severe Adverse Effects	Hepatocellular injury
Severe Drug-Drug Interactions	Consider a reduction in cannabidiol dosage when co-administered with a moderate or strong inhibitor of CYP3A4 or CYP2C19. Consider an increase in dose when co-administered with a strong CYP3A4 or CYP2C19 inducer. Concomitant use with valproate increases the incidence of liver enzyme elevations. Concomitant use with CNS depressants may increase the risk of sedation and somnolence.
Severe Drug-Food Interactions	Co-administration with high-fat/high-calorie meal increased Cmax by 5-fold, AUC by 4-fold, and reduced the total variability, compared with the fasted state in healthy volunteers.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Assess ALT, AST and total bilirubin levels prior to starting treatment, at 1 month, 3 months, and 6 months after initiation of treatment, and periodically thereafter or as clinically indicated, as well as within 1 month following dosage changes and addition of or changes in medications that are known to impact the liver. Consider more frequent monitoring in patients taking valproate or who have elevated liver enzymes at baseline.
Used in Pediatric Areas	Safety and effectiveness established in patients 2 years of age and older.
Renal or Hepatic Dosing	Hepatic dosing: No dose adjustment required in patients with mild hepatic impairment (Child-Pugh A). For moderate impairment, recommended starting dose is 1.25 mg/kg twice daily, and maintenance dose is 2.5 mg/kg twice daily (max 5 mg/kg twice daily). For severe impairment, recommended starting dose is 0.5 mg/kg twice daily, and maintenance dose is 1 mg/kg twice daily (max 2 mg/kg twice daily).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients who are hypersensitive to cannabidiol or any of the ingredients in Epidiolex. Warnings for hepatocellular injury, somnolence and sedation, suicidal behavior and ideation, withdrawal of antiepileptic drugs.
Special administration technique or considerations	Use a 5 mL or 1 mL calibrated oral syringe to measure and deliver the prescribed dose accurately. Administer consistently with or without food. Discard any unused product 12 weeks after first opening the bottle.
Prepared by	Sunao Tamukai, Hannah Sanchez
Source	Epidiolex (cannabidiol) [prescribing information]. Carlsbad, CA: GW Research LTD, June 2018.

Encorafenib / Braftovi / Array Biopharma Inc	
Generic Name / Brand Name / Company	Encorafenib / Braftovi / Array Biopharma Inc
Date of approval	6/27/18
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor
Indication	In combination with binimetinib for treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation.
Comparative agent – Therapeutic interchange?	Dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf)
Dosage forms/strengths. Common Dose/sig	Capsules: 50 mg and 75 mg. The recommended dose is 450 mg orally once daily in combination with binimetinib.
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medication Names	binimetinib, dabrafenib, trametinib, vemurafenib
Clinical Use Evaluation	
Common Adverse Effects	>25%: fatigue, nausea, vomiting, abdominal pain, and arthralgia
Severe Adverse Effects	Hemorrhage, QT prolongation, uveitis, hepatotoxicity, and new primary malignancies.
Severe Drug-Drug Interactions	Strong or moderate CYP3A4 inhibitors: Concomitant use may increase encorafenib plasma concentration. If concomitant use cannot be avoided, modify encorafenib dose. Strong or moderate CYP3A4 inducers: Concomitant use may decrease encorafenib plasma concentrations. Avoid concomitant use. Sensitive CYP3A4 substrates: Concomitant use with encorafenib may increase toxicity or decrease efficacy of these agents. Avoid hormonal contraceptives.
Severe Drug-Food Interactions	Avoid grapefruit during encorafenib treatment.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor electrolytes before and during treatment. Correct electrolyte abnormalities and control for cardiac risk factors for QT prolongation.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients.
Renal or Hepatic Dosing	No adjustment in mild hepatic impairment or mild to moderate renal impairment; dose recommendations not available for patients with moderate or severe hepatic impairment or severe renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Warnings and precautions include risks for development of new primary malignancies, tumor promotion in BRAF wild-type tumors, hemorrhage, uveitis, QT prolongation, and embryo-fetal toxicity.
Special administration technique or considerations	Use in combination with binimetinib; if binimetinib is withheld, reduce encorafenib dose. Consult prescribing information for recommended dose modifications in response to adverse reactions.
Prepared by	Hannah Sanchez, Sunao Tamukai
Source	Braftovi (encorafenib) [prescribing information]. Boulder, CO: Array Biopharma Inc, June 2018.

Binimetinib / Mektovi / Array Biopharma Inc	
Generic Name / Brand Name / Company	Binimetinib / Mektovi / Array Biopharma Inc
Date of approval	6/27/18
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor
Indication	In combination with encorafenib for treatment of patients, with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation.
Comparative agent – Therapeutic interchange?	Dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf)
Dosage forms/strengths. Common Dose/sig	Tablets: 15 mg. The recommended dose is 45 mg orally twice daily in combination with encorafenib.
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medication Names	Encorafenib, dabrafenib, trametinib, vemurafenib
Clinical Use Evaluation	
Common Adverse Effects	>25%: fatigue, nausea, diarrhea, vomiting, and abdominal pain.
Severe Adverse Effects	Cardiomyopathy, venous thromboembolism, hemorrhage, ocular toxicities, rhabdomyolysis, hepatotoxicity, and interstitial lung disease.
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.	Assess ejection fraction by echocardiogram or MUGA scan prior to initiating treatment, one month after initiating treatment, and then every 2 to 3 months during treatment. Monitor liver laboratory tests before initiation, monthly during treatment, and as clinically indicated. Monitor CPK and creatinine levels prior to initiating, periodically during treatment, and as clinically indicated.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients.
Renal or Hepatic Dosing	For patients with moderate or severe hepatic impairment the recommended dose is 30 mg orally twice daily.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Warnings and precautions include cardiomyopathy, venous thromboembolism, hemorrhage, ocular toxicities, rhabdomyolysis, hepatotoxicity, interstitial lung disease, and embryo-fetal toxicity.
Special administration technique or considerations	Use in combination with encorafenib; if encorafenib is discontinued, discontinue binimetinib. Consult prescribing information for recommended dose modifications in response to adverse reactions.
Prepared by	Hannah Sanchez, Sunao Tamukai
Source	Mektovi (binimetinib) [prescribing information]. Boulder, CO: Array Biopharma Inc, June 2018.

Glycopyrronium / Qbrexza / Dermira	
Generic Name / Brand Name / Company	Glycopyrronium / Qbrexza / Dermira
Date of approval	6/29/18
Drug Class (Mechanism of Action if novel agent)	Anticholinergic
Indication	Treatment of adults and children as young as age 9 years who have primary axillary hyperhidrosis
Comparative agent – Therapeutic interchange?	Prescription antiperspirants: 20% aluminum chloride hexahydrate, 6.25% aluminum chloride hexahydrate
Dosage forms/strengths. Common Dose/sig	Single-use cloth pre-moistened with 2.4% glycopyrronium solution. Apply once daily on both axillae using a single cloth. For topical use only.
DEA Schedule	Not applicable
Date of market availability	October 2018
Similar Medication Names	Qbrelis
Clinical Use Evaluation	
Common Adverse Effects	>2%: dry mouth, mydriasis, oropharyngeal pain, headache, urinary hesitation, vision blurred, nasal dryness, dry throat, dry eye, dry skin, constipation. Local skin reactions, including erythema, burning/stinging and pruritus.
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Coadministration with other anticholinergic medications may result in an increase in anticholinergic adverse effects. Avoid coadministration with other anticholinergic-containing drugs
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 efficacy are not established in patients under 9 years of age
Renal or Hepatic Dosing	The elimination of glycopyrronium is severely impaired in patients with renal failure. There are no dose adjustments recommended at this time.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with medical conditions that can be exacerbated by the anticholinergic effect of glycopyrronium (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjogren's syndrome). Warnings for worsening of urinary retention, control of body temperature, and operating machinery or an automobile.
Special administration technique or considerations	Tear open the pouch and pull out the cloth, unfold the cloth, and wipe it across one entire underarm once. Using the same cloth, wipe the other underarm once. Wash hands immediately with soap and water after applying and discarding the cloth. Do not apply to broken skin. Avoid using with occlusive dressings
Prepared by	Sunao Tamukai, Hannah Sanchez
Source	Qbrexza (glycopyrronium) [prescribing information]. Menlo Park, CA: Dermira Inc, June 2018.