January 2020 Drug Update

CastiaRx™
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New Drug Approvals

Approval Date	Label Name	Generic Name	Strength	Dosage Form	Use	Launch
01/09/2020	**Ayvakit®**	avapritinib	100 mg 200 mg 300 mg	Tablet	Intestinal Cancer	01/09/2020
01/10/2020	Valtoco®	diazepam	5 mg 7.5 mg 10 mg	Nasal Spray	Seizure	01/13/2020
01/21/2020	Tepezza®	teprotumumab-trbw	500 mg	IV Solution	Thyroid Eye Disease	01/28/2020

Newly Available Brand Drugs

Approval Date	Label Name	Generic Name	Strength	Dosage Form	Use	Launch
07/17/2019	Recarbrio®	imipenem cilastatin relebactam	1.25 gm (500-500-250 mg)	IV Solution	Antibacterial	01/06/2020
11/05/2019	Absorica LD®	isotretinoin	8 mg 16 mg 24 mg 32 mg	Capsule	Acne	01/13/2020
06/28/2019	**Zirabev®**	bevacizumab-bvzr	100 mg/4 mL 400 mg/16mL	IV Solution	Colorectal Cancer	01/13/2020
03/27/2019	Jatenzo®	testosterone undecanoate	158 mg 198 mg 237 mg	Capsule	Testosterone Replacement	01/14/2020
10/11/2019	Secuado®	asenapine	3.8 mg 5.7 mg 7.6 mg	Transdermal Patch	Schizophrenia	01/15/2020

*Specialty medications are listed in **bold** type

12/20/2019	Caplyta®	lumateperone	42 mg	Capsule	Schizophrenia	01/17/2020
12/23/2019	Ubrelvy®	ubrogepant	50 mg, 100 mg	Tablet	Migraine	01/17/2020
11/04/2019	Talicia®	omeprazole amoxicillin rifabutin	250 mg 12.5 mg 10 mg	Capsule	H. Pylori Infection	01/20/2020

First Time Generic Approvals

Label Name	Generic Name	Strength	Dosage Form	Use
Silenor®	doxepin	3 mg 6 mg	Tablet	Insomnia
Depen®	penicillamine	250 mg	Tablet	Wilson's Disease
Zohydro® ER	hydrocodone ER	10 mg 15 mg 20 mg 30 mg 40 mg 50 mg	Capsule	Pain

New Uses

Drug Name or Class	Previous Use	New Use
Ozempic® (semaglutide)	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

*Specialty medications are listed in **bold** type

Safety Updates and Recalls

Drug Name or Class	Use	Description	Impact
ranitidine	Stomach Acid Reducer	Voluntary recall due to potential NDMA amounts above levels established by the FDA	Consumers advised to discontinue use and consult with health care provider about treatment options.
nizatidine-Mylan	Stomach Acid Reducer	Voluntary recall of three lots due to potential NDMA amounts above levels established by the FDA	Consumers advised to contact Stericycle for return of the recalled product.
lamotrigine-Taro	Seizures	Voluntary recall of a single lot due to a cross-contamination with a small amount of another drug substance (enalapril maleate) used to manufacture another product at the same facility.	Consumers that have any quantities of lamotrigine 100 mg lot# 331771 (exp. 6-21) should stop using the product and return it to the pharmacy that dispensed it.

*Specialty medications are listed in **bold** type

References:

1. U.S. Food and Drug Administration. Novel Drug Approvals for 2020. Available at: https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020. Updated January 24, 2020. Accessed January 24, 2020.
2. U.S. Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/. Updated January 24, 2020. Accessed January 24, 2020.
3. U.S.National Library of Medicine. DailyMed. https://dailymed.nlm.nih.gov/dailymed/. Accessed January 24, 2020.
4. Appco Pharma LLC issues voluntary nationwide recall of ranitidine hydrochloride capsules 150 mg and 300 mg due to an elevated amount of unexpected impurity, N-Nitrosodimethylamine (NDMA). U.S. FDA MedWatch. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/appco-pharma-llc-issues-voluntary-nationwide-recall-ranitidine-hydrochloride-capsules-150-mg-and-300. Updated January 7, 2020. Accessed January 24, 2020.
5. Mylan Initiates Voluntary Nationwide Recall of Three Lots of Nizatidine Capsules, USP, Due to the Detection of Trace Amounts of NDMA (N-Nitrosodimethylamine) Impurity Found in the Active Pharmaceutical Ingredient Manufactured by Solara Active Pharma Sciences Limited. U.S. FDA MedWatch. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mylan-initiates-voluntary-nationwide-recall-three-lots-nizatidine-capsules-usp-due-detection-trace. Updated January 8, 2020. Accessed January 24, 2020.
6. Denton Pharma, Inc. dba Northwind Pharmaceuticals Voluntarily Recalls All Unexpired Lots of its Ranitidine Tablets and Ceases Distribution, Due to Possible Presence of N-nitrosodimethylamine (NDMA) Impurity. U.S. FDA MedWatch. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/denton-pharma-inc-dba-northwind-pharmaceuticals-voluntarily-recalls-all-unexpired-lots-its. Updated January 8, 2020. Accessed January 24, 2020.
7. Taro Pharmaceuticals U.S.A., Inc. Issues Voluntary Nationwide Recall of Lamotrigine Tablets USP, 100 mg, 100 Count Bottles. U.S. FDA MedWatch. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/taro-pharmaceuticals-usa-inc-issues-voluntary-nationwide-recall-lamotrigine-tablets-usp-100-mg-100. Updated January 10, 2020. Accessed January 24, 2020.

*Specialty medications are listed in **bold** type