PERFORMRx℠

# Drug Information Update

April 2022

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## NEWLY AVAILABLE GENERICS

| Generic Name/ Dosage Form | Brand Name | Manufacturer | Indication |
|---|---|---|---|
| Hyclodex | hypoc acid/sod hypo/nacl/water 0.012 %-0.002 %-0.046 %-99.94 % spray | Marnel Pharm | Intented to be used under the supervison of a health care professional for cleaning and removal of microorganisms, debris, and foreign material affecting various dermatologic skin conditions.<br>*Medical Device |
| Abraxane | paclitaxel protein-bound 100mg vial | Celgene/BMS | • Metastatic Breast Cancer: for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.<br>• Non-Small Cell Lung Cancer: for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.<br>Adenocarcinoma of the Pancreas: for the first-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine. |
| Vimpat | lacosamide 200 mg/20 mL vial | UCB Pharma | • Treatment of partial-onset seizures in patients 1 month of age and older.<br>• Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older. |
| BiDil | isosorbide dinitrate/hydralazine 20 mg-37.5 mg tablet | Arbor | Treatment of heart failure as an adjunct therapy to standard therapy in self-identified black patients to improve survival, prolong time to hospitalization for heart failure and to improve patient-reported functional status. |

| Generic Name/ Dosage Form | Brand Name | Manufacturer | Indication |
|---|---|---|---|
| Apokyn | apomorphine hcl 10 mg/mL cartridge | US WorldMeds | Acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease |

## NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

| Drug Name | Generic Name | Description | Comments |
|---|---|---|---|
| cefazolin 2 gram solution for injection | cefazolin sodium | New strength solution for injection | New Strength |
| Nuwiq 1,500 unit intravenous solution | antihemoph.fviii, hek b-delete | New strength factor product | New Strength |
| Mayzent 1 mg tablet | siponimod | New 1 mg tablet for maintenance dosage in patients with a CYP2C9*1/*3 or *2/*3 genotype | New Strength |
| Mayzent Starter Pack (for 1 mg maint dose) 0.25 mg (7 tabs) tablets | siponimod | New starter pack | Starter Pack for 1 mg Maintenance Dosage |
| Rinvoq 45 mg tablet, extended release | upadacitinib | New strength Rinvoq due to new indication for UC. | New Strength |
| Opdualag 240 mg-80 mg/20 mL intravenous solution | nivolumab-relatlimab-rmbw | A programmed PD-1 blocking antibody, andLAG-3 blocking antibody combination, indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. | New Entity and Combination |
| Sanofi COVID-19 Vaccine Booster-Antigen Component(PF) IM emulsion | covid-19 vaccine (sanofi)/pf | Unapproved COVID-19 vaccine | New Entity; Waiting FDA review, not available until EUA granted |
| Pluvicto 27 mCi/mL (1,000 MBq/mL) intravenous solution | lu-177 vipivotide tetraxetan | The first FDA-approved targeted radioligand therapy for eligible patients with mCRPC that combines a targeting compound (ligand) with a therapeutic radioisotope (a radioactive particle). Approved for PSMA-positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy. | New Entity |

| Drug Name | Generic Name | Description | Comments |
|---|---|---|---|
| nalmefene 1 mg/mL injection solution | nalmefene hcl | New dosage form; opioid overdose reversal agent | New Dosage Form; Other dose forms/strengths of nalmefene have been obsolete since 2008 |
| Ozempic 2 mg/dose (8 mg/3 mL) subcutaneous pen injector | semaglutide | New strength due to approval of higher dose regimen for type 2 diabetes | New Strength |
| ProvayBlue 5 mg/mL intravenous solution | methylene blue | New dosage form (vial) of methylene blue | New Dosage Form |
| Verkazia 0.1 % eye drops in a dropperette | cyclosporine | Ophthalmic emulsion is a calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis (VKC), a chronic allergic inflammation of the eye, in children and adults. 505(b)2. Usually treated first line w/mast cell stabilizers (cromolyn, lodoxamide) but calcineurin inhibitors are used in refractory dz. This is the first ophthalmic calcineurin inhibitor with a labeled indication for VKC. | New Strength |
| Tlando 112.5 mg capsule | testosterone undecanoate | Oral testosterone replacement therapy for hypogonadism in adult males. 505(b)(2) approval. | New Strength |
| Triumeq PD 60 mg-5 mg-30 mg tablet for oral suspension | abacavir/dolutegravir /lamivudine | New tablets for oral suspension for treatment of HIV; approval expansion for patients with smaller minimum weight (at least 10 kg). | New Dosage Form and Strength |
| Quviviq 25, 50 mg tablet | daridorexant hcl | A dual orexin receptor antagonist for insomnia characterized by difficulties with sleep onset and/or sleep maintenance. | New Entity |
| Vijoice 50, 125 mg tablet | alpelisib | First FDA approved treatment for treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. | New Strength |

| Drug Name | Generic Name | Description | Comments |
|---|---|---|---|
| | | Alpelisib is also marketed under brand name Piqray for breast cancer. | |
| Vijoice 250 mg/day (200 mg x 1-50 mg x 1) tablet | alpelisib | First FDA approved treatment for treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. Alpelisib is also marketed under brand name Piqray for breast cancer. | New Daily Dose Package Size |
| Paxlovid (EUA) 150 mg-100 mg tablet | nirmatrelvir/ritonavir | New dose pack for patients with renal impairment | New Dose Pack for patients with renal impairment |

## NEW INDICATIONS (EXISTING DRUGS)

†**Bolded** items reflect newly approved indication; ~~strikethrough~~ of removed indication/age limit/etc.

| Brand Name | Generic Name/ Dosage Form | Manufacturer | Newly Approved Indication† |
|---|---|---|---|
| Rinvoq | upadacitinib extended-release tablets, 15 mg, 30 mg, 45 mg | AbbVie | • Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers.<br>• Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.<br>• Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.<br>• Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. |
| Keytruda | pembrolizumab injection, 100 mg/4 mL solution in a single-dose vial | Merck | As a single agent, for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.<br>Note: Keytruda has many other indications not presented here because there were no changes |
| Smoflipid | injection, lipid injectable emulsion with a lipid content of 0.2 g/mL in 100 mL, 250 mg, 500 mL flexible containers and 1000 mL pharmacy bulk package | Fresenius Kabi | Indicated in adult and pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. |
| Fintepla | Fenfluramine oral solution, 2.2 mg/mL | Zogenix | Treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older |

| Brand Name | Generic Name/ Dosage Form | Manufacturer | Newly Approved Indication† |
|---|---|---|---|
| Edurant | Rilpivirine tablets, 25 mg | Janssen | EDURANT is a human immunodeficiency virus type 1 (HIV-1) specific, non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients 12 years of age and older and weighing at least 35 kg with HIV-1 RNA less than or equal to 100,000 copies/mL.<br>Limitations of Use:<br>• More EDURANT treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure (HIV-1 RNA ≥50 copies/mL) compared to EDURANT treated subjects with HIV-1 RNA less than or equal to 100,000 copies/mL.<br><br>EDURANT is indicated in combination with VOCABRIA (cabotegravir), for short-term treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. |
| Vocabria | Cabotegravir tablets, 30 mg | | HIV-1 Treatment: VOCABRIA is an HIV-1 integrase strand transfer inhibitor (INSTI) indicated in combination with EDURANT (rilpivirine) for short-term treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.<br><br>HIV-1 Pre-Exposure Prophylaxis: VOCABRIA is indicated in at-risk adults and adolescents weighing at least 35 kg for short-term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. |

| Brand Name | Generic Name/ Dosage Form | Manufacturer | Newly Approved Indication† |
|---|---|---|---|
| | | | Individuals must have a negative HIV-1 test prior to initiating VOCABRIA for HIV-1 PrEP.<br><br>VOCABRIA may be used as:<br>• oral lead-in to assess the tolerability of cabotegravir prior to administration of CABENUVA (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension) for HIV-1 treatment or APRETUDE (cabotegravir extended-release injectable suspension) for HIV-1 PrEP.<br>• oral therapy for patients who will miss planned injection dosing with CABENUVA for HIV-1 treatment or APRETUDE for HIV-1 PrEP |
| Cabenuva | cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension; 400 mg/600 mg kit, 600 mg/900 mg kit | ViiV | Treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA<50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine |
| Triumeq, Triumeq PD | Triumeq tablets, 600 mg abacavir, 50 mg dolutegravir, and 300 mg lamivudine; Triumeq PD tablets for oral suspension, 60 mg abacavir, 5 mg dolutegravir and 30 mg lamivudine | ViiV | Triumeq and Triumeq PD, a combination of dolutegravir (integrase strand transfer inhibitor [INSTI]), abacavir, and lamivudine (both nucleoside analogue reverse transcriptase inhibitors) is indicated for the treatment of HIV-1 infection in adults and in pediatric patients weighing at least 10 40 kg. |
| Yescarta | axicabtagene ciloleucel cell suspension | Kite Pharma | Yescarta is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:<br>• Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. |

| Brand Name | Generic Name/ Dosage Form | Manufacturer | Newly Approved Indication† |
|---|---|---|---|
| | | | • Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.<br>• Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). |
| Xigduo XR | dapagliflozin and ER metformin hydrochloride 2.5 mg-1000 mg, 5 mg-500 mg, 5 mg-1000 mg, 10 mg-500 mg, 10 mg-1000 mg tablets | AstraZeneca | A combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.<br><br>Dapagliflozin is indicated to reduce:<br>• the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.<br>• the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.<br>• the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.<br>Limitations of use:<br>• Not for treatment of type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.<br>• Because of the metformin component, the use of Xigduo XR is limited to adults with type 2 diabetes mellitus for all indications. |

| Brand Name | Generic Name/ Dosage Form | Manufacturer | Newly Approved Indication† |
|---|---|---|---|
| | | | • Xigduo XR is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for the treatment of kidney disease. Xigduo XR is not expected to be effective in these populations. |
| Lupron Depot | Leuprolide acetate for depot suspension; 7.5 mg, 22.5 mg, 30 mg, and 45 mg injections in a kit with prefilled dual chamber syringe | AbbVie | Palliative treatment of advanced prostatic cancer. |

## RECALLS

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| Meclizine Hydrochloride Tablets USP, 12.5 mg, packaged in a case of 24 bottles (100-count bottle), Rx only, Manufactured by: Jubilant Cadista Pharmaceuticals, Inc., Salisbury, MD, 21801, NDC 59746-122-06 | Class I | Drugs | Lot # 22P0036, Exp 12/2024 | Labeling: Label mix-up: Incorrect label placed on product. Shipper cases labeled Meclizine Hydrochloride Tablets contain bottles incorrectly labeled as PredniSONE Tablets. The tablets in the bottles are Meclizine Hydrochloride | Jubilant Cadista Pharmaceuticals, Inc. |
| SYMJEPI (epinephrine injection, USP) 0.3 mg, (0.3 mg/0.3 mL), Two Pre-Filled Single-Dose Syringes per carton, Rx Only, Manufactured for Adamis Pharmaceuticals Corp.; San Diego, CA 92130; Distributed by USWM, LLC., Louisville, KY 40241, Made in Belgium, NDC 78670-130-02 | Class I | Drugs | Lot #: 21041W, Exp. 8/31/2022; 21081W, Exp. 11/30/2022; 21102W, Exp. 2/28/2023 | Defective Delivery System: Potential clogging of the needle preventing the dispensing of epinephrine. | Adamis Pharmaceuticals Corporation |
| SYMJEPI (epinephrine injection, USP) 0.15 mg (0.15 mg/0.3 mL), Two Pre-Filled Single-Dose Syringes per carton, Rx Only, Manufactured for Adamis Pharmaceuticals Corp.; San Diego, CA 92130; Distributed by USWM, LLC., Louisville, KY 40241, Made in Belgium, NDC 78670-131-02. | Class I | Drugs | Lot # 21101Y, Exp. 11/30/2022 | Defective Delivery System: Potential clogging of the needle preventing the dispensing of epinephrine. | Adamis Pharmaceuticals Corporation |
| IDArubicin Hydrochloride Injection USP 5gm/5mL (1mg/mL), 5mL Single Dose Vial, Rx Only, Teva Pharmaceuticals, USA, Inc., North Wales, PA 19454, NDC 0703-4154-11. | Class I | Drugs | Lot #: 31329657B, Exp. Date 08/2023 | Presence of Particulate Matter: Product was found to contain silica and iron oxide | Teva Pharmaceuticals USA Inc |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| GONADORELIN (5ML) 0.2 MG/ML INJECTABLE, Packaged in a multi dose 10ML vial, Formula ID132227, APS Pharmacy | Class II | Drugs | Lots: 745708 BUD: 6/21/2022; 753364 BUD: 7/27/2022; 752508 BUD: 7/24/2022; 750313 BUD: 7/16/2022; 753020 BUD: 7/26/2022; 747712 BUD: 7/4/2022; 747974 BUD: 7/5/2022; 754802 BUD: 8/3/2022; 751158 BUD: 7/19/2022; 756837 BUD: 8/16/2022; 748939 BUD: 7/10/2022; 750842 BUD: 7/18/2022; 755742 BUD: 8/8/2022; 758691 BUD: 8/28/2022; 758432 BUD: 8/27/2022; 758975 BUD: 8/29/2022; 756643 BUD: 8/15/2022 | Lack of sterility assurance. | Drug Depot, Inc., dba APS Pharmacy |
| (CA) GONADORELIN (4ML) 0.2 MG/ML INJECTABLE, Packaged in a multi dose 10ML vial, Formula ID136345, APS Pharmacy | Class II | Drugs | Lots: 749842 BUD: 7/13/2022; 749568 BUD: 7/12/2022; 752053 BUD: 7/23/2022; 752817 BUD: 7/25/2022; 757404 BUD: 8/21/2022; 757915 BUD: 8/23/2022; 757321 BUD: 8/20/2022; 753718 BUD: 7/30/2022 | Lack of sterility assurance. | Drug Depot, Inc., dba APS Pharmacy |
| TESTOSTERONE CYPIONATE/ANASTROZOLE *GS* OIL 200MG/1MG/ML Injectable, Packaged in a multi dose 10ML vial, as a) 4 | Class II | Drugs | Lots: a) 745383 BUD: 6/20/2022; 759295 BUD: 8/30/2022; b) 745749 | Lack of sterility assurance. | Drug Depot, Inc., dba APS Pharmacy |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| ML Formula ID 115387; b) (RM) 10 ML Formula ID 115125; APS Pharmacy | | | BUD: 6/21/2022; 746272 BUD: 6/27/2022 | | |
| TESTOSTERONE CYPIONATE/ ANASTROZOLE *GS* OIL (10ML) 200MG/0.5MG/ML; Packaged in a multi dose 10ML vial, as a) (CA) 4 ML Formula ID 136164; b) (RM) 10 ML Formula ID 115962; APS Phar | Class II | Drugs | Lots: a)750851 BUD: 7/18/2022; b) 754549 BUD: 8/2/2022 | Lack of sterility assurance. | Drug Depot, Inc., dba APS Pharmacy |
| TESTOSTERONE CYPIONATE/ DHEA *GS* 200/10MG/ML Injectable, Packaged in a multi dose 10ML vial, as a) 5 ML Formula ID 115678; b) 10 ML Formula ID 115498, APS Pharmacy | Class II | Drugs | Lots: a)746000 BUD: 6/26/2022; b) 751472 BUD: 7/20/2022 | Lack of sterility assurance. | Drug Depot, Inc., dba APS Pharmacy |
| TESTOSTERONE CYPIONATE/PROPIONATE *SES* Oil (10 ML) 160MG/20MG/ML Injectable, Packaged in a multi dose 10ml vial, Formula ID 115498, APS Pharmacy | Class II | Drugs | Lot:759312 BUD: 8/30/2022 | Lack of sterility assurance. | Drug Depot, Inc., dba APS Pharmacy |
| TESTOSTERONE CYPIONATE *GS* Oil 200 MG/ML Injectable, Packaged in a multi dose 10ML vial, Formula ID 76681, APS Pharmacy | Class II | Drugs | Lot: 754381 BUD: 8/1/2022 | Lack of sterility assurance. | Drug Depot, Inc., dba APS Pharmacy |
| TESTOSTERONE CYPIONATE *GS* (2 mL) 80 MG/ML Injectable, Packaged in a multi dose 10ML vial, Formula ID 127492, APS Pharmacy | Class II | Drugs | Lot: 746269 BUD: 6/27/2022 | Lack of sterility assurance. | Drug Depot, Inc., dba APS Pharmacy |
| Glycopyrrolate Tablets, USP, 1 mg, 100-count bottle, Rx Only, Distributed by: Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520, NDC 13107-014-01. | Class II | Drugs | Lot: 01421008A1, Exp 03/2023 | Presence of Foreign Substance: Complaint for pieces of glass discovered in a sealed bottle which came from equipment within the packaging room. | Aurolife Pharma, LLC |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| Lansoprazole Delayed-Release Capsules, USP, 15 mg, a) 30-count bottle, (NDC 55111-398-30), b) 90-count bottle, (55111-398-90), Rx Only, Manufactured. By: Dr. Reddy's Laboratories Limited, Bachupally - 500 090, India | Class II | Drugs | Lot # a) C2103093, Exp. 12/2023; b)C2103092, Exp. 12/2023. | Failed Dissolution Specifications; during long term stability testing. | Dr. Reddy's Laboratories, Inc. |
| Lansoprazole Delayed-Release Capsules, USP, 30 mg, 90-count bottle, Rx Only, Manufactured By: Dr. Reddy's Laboratories Limited, Bachupally - 500 090, India, NDC 55111-399-90. | Class II | Drugs | Lot# C2102911, Exp. 12/2023 | Failed Dissolution Specifications; during long term stability testing. | Dr. Reddy's Laboratories, Inc. |
| Orphenadrine Citrate Extended-Release Tablets, USP 100 mg, Rx Only, 100 Tablets, Manufactured by Sandoz Inc., Princeton, NJ 08540 NDC 0185-0022-01. | Class II | Drugs | Lot #: JX6411, JX6413, Exp. 05/2022 Lot #: KC0723,KC3303, Exp. 08/2022 Lot #: KE4348, KE7169,KE4349, Exp. 11/2022 Lot #: KL3199, KM0072,KS3939, Exp. 03/2023 Lot #: LA7704, LA7703,LA9243, Exp. 11/2023 | CGMP Deviations:Nitrosamine impurity (NMOA) above the acceptable daily limit. | Sandoz, Inc |
| TETRACAINE 1% Tetracaine HCl Injection, USP, 20mg/2mL (10mg/mL), 10 x 2ml Single Use Vials per box, Rx only, Manufactured for Cameron Pharmaceuticals, LLC., NDC 42494-437-10. | Class II | Drugs | Lot #: 21VTHI017, 21VTHI018, 21VTHI019, Exp 5/31/2023 | Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile. | Vitae Enim Vitae Scientific, Inc. |
| PAPAVERINE HYDROCHLORIDE Injection, USP, 60 mg/2mL (30 mg/mL), packaged as a) 25 x 2mL Single Use Vials per box (NDC 72516-024-25) and b) 10 x 2mL Single Use | Class II | Drugs | Lot #: a) 20VPHI037, 20VPHI038, 20VPHI039, Exp 12/31/2022; 21VPHI021, 21VPHI022, | Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) | Vitae Enim Vitae Scientific, Inc. |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| Vials per box (NDC 72516-024-10); Manufactured for Oryza Pharmaceuticals, Inc. | | | 21VPHI023, Exp 6/30/2023; 21VPHI047, 21VPHI048, Exp 10/31/2023; b) 21VPHI023, Exp 6/30/2023 | that call into question the sterility of products intended to be sterile. | |
| PHENOBARBITAL Sodium Injection, USP, 65mg/mL, packaged as a) 25 x 1 mL Vials per box (NDC 42494-415-25) and b) 3 x 1 mL Vials per box (NDC 42494-415-03), Rx only, Manufactured for Cameron Pharmaceuticals, LLC. | Class II | Drugs | Lot #: a) 20VPSI007, Exp 3/31/2022; 20VPSI015, Exp 5/30/2022; 20VPSI018, Exp 6/1/2022; 20VPSI032, Exp 11/30/2022; 21VPSI002, 21VPSI003, Exp 1/31/2023; 21VPSI006, Exp 3/31/2023; 21VPSI012, 21VPSI020, Exp 5/31/2023; 21VPSI035, Exp 7/31/2023; 21VPSI037, 21VPSI038, Exp 8/31/2023; 21VPSI043, 21VPSI044, Exp 10/31/2023; 21VPSI050, 21VPSI051, Exp 11/30/2023; 22VPSI004, Exp 7/31/2024; 22VPSI006, Exp 8/31/2024; b) 20VPSI008, Exp 3/31/2022; 20VPSI019, Exp | Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile. | Vitae Enim Vitae Scientific, Inc. |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| | | | 6/30/2022; 21VPSI050, Exp 11/30/2023, | | |
| PHENOBARBITAL Sodium Injection, USP, 130 mg/mL, packaged as a) 25 x 1 mL Vials per box (NDC 42494-416-25) and b) 3 x 1mL Vials per box (NDC 42494-416-03), Rx only, Manufactured for Cameron Pharmaceuticals, LLC. | Class II | Drugs | Lot # a) 20VPSI011, Exp. 4/30/2022; 20VPSI014, Exp. 5/31/2022; 20VPSI020, 20VPSI022, 20VPSI023, Exp. 7/31/2022; 21VPSI007, Exp. 3/31/2023; 21VPSI013, Exp. 5/31/2023; 21VPSI027, Exp. 6/30/2023; 21VPSI039, Exp. 8/31/2023; 21VPSI042, Exp. 10/31/2023; 21VPSI049, Exp. 11/30/2023; 21VPSI052, Exp. 12/31/2023; 22VPSI005, Exp. 7/31/2024; 22VPSI007, Exp. 8/31/2024; Lots: b) 22VPSI007, Exp. 8/31/2024; 20VPSI009, Exp. 3/31/2022; 20VPSI020, Exp. 7/31/2022; 21VPSI039, Exp. 8/31/2023; 22VPSI005, Exp. 7/31/2024. | Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile. | Vitae Enim Vitae Scientific, Inc. |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| Sucralfate Oral Suspension, USP 1g/10mL, packaged in a) 40 case of 10 mL unit Dose Cups (NDC 69339-148-17) and b) 100 case of 10 mL Unit Dose Cups (NDC 69339-148-19) Rx Only, Dash Pharmaceuticals, Upper Saddle River, NJ 07458. | Class II | Drugs | Lot #: a) 376908P40, Exp. Date 02/28/2023; b) 376908P100, Exp. Date 02/28/2023 | Labeling: Label Mix-Up | DASH Pharmaceuticals LLC |
| Accuretic (quinapril HCl/hydrochlorothiazide) Tablets, 10 mg/12.5 mg*, 90 Tablets bottles, Rx Only, Distributed by: Parke-Davis, Division of Pfizer Inc, NY, NY 10017, Made in Germany, NDC 0071-3112-23. | Class II | Drugs | Lot FG5379; Exp. 08/2024 | CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit. | Pfizer Inc. |
| Accuretic (quinapril HCl/hydrochlorothiazide) Tablets 10 mg/12.5 mg 90 tablets bottle, Rx Only, Distributed by: Parke-Davis, Division of Pfizer Inc, NY, NY 10017, Made in Germany, NDC 0071-0222-23 | Class II | Drugs | Lot EA6686; Exp. 04/2022 | CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit. | Pfizer Inc. |
| Accuretic (quinapril HCl/hydrochlorothiazide) Tablets, 20 mg/12.5 mg, 90 tablets bottles, Rx Only Distributed by: Parke-Davis, Division of Pfizer Inc, NY, NY 10017, Made in Germany, NDC 0071-0220-23. | Class II | Drugs | Lot EA6665, Exp Date 04/2022, Lot CN0640, Exp Date 04/2022 | CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit. | Pfizer Inc. |
| Accuretic (quinapril HCl/hydrochlorothiazide) Tablets, 20 mg/25 mg, 90 tablets bottles, Rx Only, Distributed by: Parke-Davis, Division of Pfizer Inc, NY, NY 10017, Made in Germany, NDC 0071-0223-23. | Class II | Drugs | Lot ET6974; Exp. 02/2023 | CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit. | Pfizer Inc. |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| quinapril and hydrochlorothiazide tablets, 20 mg/25 mg*, 90 Tablets bottles, Rx Only, Distributed by: Greenstone, LLC, Peapack, NJ, 07977, Made in Germany, NDC 59762-5225-9 | Class II | Drugs | Lot FE3714; Exp. 02/2023 | CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit. | Pfizer Inc. |
| quinapril HCl/hydrochlorothiazide tablets, 20 mg/12.5 mg*, 90 Tablets bottles, Rx Only, Distributed by: Greenstone, LLC, Peapack, NJ, 07977, Made in Germany, NDC 59762-0220-1 | Class II | Drugs | Lots DN6931, ED3904 & ED3905; Exp. 03/2023 | CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit. | Pfizer Inc. |
| quinapril HCl/hydrochlorothiazide tablets, 20 mg/25 mg*, 90 Tablets, Rx Only, Distributed by: Greenstone, LLC, Peapack, NJ, 07977, Made in Germany, NDC 59762-0223-1 | Class II | Drugs | Lot DP3414; Exp 02/2023 | CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit. | Pfizer Inc. |
| Accuretic (quinapril HCl/hydrochlorothiazide) tablets, 20 mg/12.5 mg*, 90 Tablets, Rx Only, Distributed by: Parke-Davis, Division of Pfizer Inc., NY. NY 10017, Made in Germany, NDC 0071-5212-23 . | Class II | Drugs | Lot FG5381; Exp. 08/2024 | CGMP Deviations: N-nitroso-quinapril and N-nitroso-hydrochlorothiazide impurity above the acceptable daily intake limit. | Pfizer Inc. |
| The Natural Dentist Healthy Breath Antiseptic Rinse, Cool Mint, 16.9 FL OZ (500 mL, Manufactured for Revive Personal Products Company, Madison, NJ 07940, UPC Code 714132000714. | Class II | Drugs | Lot #: 3640A, Exp 12/22 | Labeling; Label mix-up and Wrong Bar Code; back label incorrectly states active ingredient as Peppermint Oil and Sage Oil and has the wrong UPC | Revive Personal Products Company |
| Janumet (sitagliptin and metformin HCl) tablets, 50 mg/500 mg, 14-count bottle, packaged as 2 bottles per carton , Sample-Not For Sale, Rx Only, Manufactured for | Class II | Drugs | Lot: U015824, Exp. 09/22. | Presence of foreign substance: Presence of stainless steel particulates in tablets. | MERCK SHARP & DOHME CORP |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. Whitehouse Station, NJ 08889, USA, by Patheon Puerto Rico, Inc. Manati, Puerto Rico, 00674 Bottle (NDC 0006-0575-02), Carton (NDC 0006-0575-03) | | | | | |
| Travoprost Ophthalmic Solution, USP, 0.004%, 2.5 mL bottle, Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505, NDC 0378-9651-32. | Class II | Drugs | Lot # TV11W101, Exp Mar 2023 | Subpotent Drug and Failed Impurities/Degradation Specifications: low out-of-specification results obtained for assay and high out-of-specification results for related substance impurities/degradation during routine stability testing. | Mylan Pharmaceuticals Inc |
| BEAK & SKIFF SANITIZER Alcohol Antiseptic 80%, Topical Solution Antiseptic Hand Rub Non-Sterile Solution, Packaged in a) 12OZ/355ML bottles, UPC 48558 94603 6 b) 5 Gallon/18,927ML pail C)1 Gallon/3,785ML jug; d)4OZ/118ML spray top bottles; Produced By; Beak & Skiff Farms Apple Farms Inc. Lafayette, NY 13084. | Class II | Drugs | Lot # 06090 | CGMP Deviations: FDA analysis found product to contain acetaldehyde above specification limits. | Beak & Skiff Cider Mill, Inc. |
| Clobetasol Propionate Lotion 0.05%, Generic for Temovate, 118 mL bottle, Rx Only, Mfg: Teligent Pharma, Inc., PREFERRED Pharmaceuticals, Inc., The Physician's Solution, NDC 68788-7768-01 | Class II | Drugs | Lot #: A0721O, A1421Y, A2121G, A2821D, B0421H, B0421I, B0521U, B1121G, B1921C, C0421B, C1821N, L0120F, L2320O, L3020T, Exp.: 4/30/2022; B2521A, C1121S, C2521U, D0121S, D0921B, D1421B, D2921C, | CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc. is discontinuing its stability study program. | Preferred Pharmaceuticals, Inc. |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| | | | E0721A, Exp.: 10/31/2022; D2221A, Exp.: 12/31/2022 | | |
| Econazole Nitrate Cream, 1%, Generic for Spectazole, 30 gm tube, Rx Only, Preferred Pharmaceuticals, Inc., The Physican's Solution, Mfg: Teligent Pharma, Inc., NDC 68788-7406-03 | Class II | Drugs | Lot #: A1122P, G1421N, Exp. 1/1/2023 | CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program. | Preferred Pharmaceuticals, Inc. |
| Preferred Pharmaceuticals, Inc. The Physician's Solution., Lansoprazole Delayed-Release Capsules, 15mg, Generic for Prevacid, 90-Count Bottle, Manufacturer: Dr Reddy's Laboratories Limited, NDC 68788-6390-09 | Class II | Drugs | Lots: H0221R, D3021T, D2221J, D1321X, Exp.12/31/2023. | Out of specification results observed in dissolution during long term stability testing. | Preferred Pharmaceuticals, Inc. |
| Clotrimazole and Betamethasone Dipropionate Cream USP, 1%/0.05%,15 g tubes, Rx only, Manufactured by: Taro Pharmaceuticals Industries Ltd. Haifa Bay, Israel 2624761, Distributed by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532, NDC 51672-4048-1 | Class III | Drugs | Lot #: AC33883, Exp. Date June 2023 | Failed Content Uniformity Specifications: Out-of-specification result for the Betamethasone Dipropionate assay of a stability sample | Taro Pharmaceuticals U.S.A., Inc. |
| Atorvstatin Calcium Tablets, USP 80 mg*, 90 Tablets, Rx Only, Mrd. By: Dr. Reddy's Laboratories Limited, Srikakulam - 532 409, INDIA, NDC 55111-124-90 | Class III | Drugs | Lot: T000707, T000756, T000758, T000759, Exp 03/2022; T2100600, T2101075, Exp. 1/2023; T2102802, Exp. 07/2023 | Failed Impurities/Degradation Specifications: Out of Specification results for related substance. | Dr. Reddy's Laboratories, Inc. |
| Risedronate Sodium Tablets, USP, 5 mg, Rx Only, 30-count bottle, Manufactured for: Macleods Pharma USA, Plainsboro, NJ 08536, Manufactured by: Macleods | Class III | Drugs | Lot #: BRD2001A, Exp 5/2022 | FAILED CONTENT UNIFORMITY SPECIFICATIONS | Macleods Pharma Usa Inc |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| Pharmaceuticals Ltd., BAddi, HImchal Pradesh, INDIA, NDC 33342-107-07. | | | | | |
| NETSPOT (kit for the preparation of Ga 68 dotatate injection) 40 mcg dotatate, kit contains Vial 1 (Reaction vial with lyophilized powder), 1 Single dose vial, consisting of 40 mcg of dotate, 5 mcg of 1,10-phenanthroline, 6 mcg of Gentisic acid, 20 mg of D-Mannitol, and Nitrogen; and Vial 2, 1 Single dose vial of reaction buffer, Rx Only, Manufactured for: Advanced Accelerator Applications USA, Inc., by: Gipharma S.r.l., Strada Crescentino snc, 13040 Saluggia (Vc), Italy, NDC 69488-001-40 | Class III | Drugs | Lot # (Vial 1)/kit: (F03221004 vial) in kit PG1921014, PG1921015, Exp 16-Mar-2022; (F03221005 vial) in kit PG1921016, PG1921017, Exp 18-Mar-2022; (F03221006 vial) in kit PG1921018, PG1921019, Exp 11-May-2022; (F03221007 vial) in kit PG1921020, PG1921021, Exp 04-Aug-2022 | Subpotent Drug: low out-of-specification results for Vial 1 assay obtained during stability studies. | Advanced Accelerator Applications USA, Inc. |
| Cequa (cyclosporine ophthalmic solution) 0.09%, packaged in 6 pouches x 10 single-use vials (0.25 mL each) per box, Manufactured for Sun Pharma Global FZE by: Laboratoire Unither, ZI de la Guerie, F-50211 Coutances Cedex, France, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 47335-506-96 | Class III | Drugs | Lot: 10014, 10016, Exp 08/2022 | Subpotent Drug and Presence of Particulate Matter: low out-of-specification results obtained for assay and the presence of particulate matter. | SUN PHARMACEUTICAL INDUSTRIES INC |
| Methylprednisolone Tablets, USP 4mg, 100-count bottle, Rx Only, Manufactured by: Jubliant Cadista Pharmaceuticals Inc. Salisbury, MD 21801, USA, NDC 59746-001-06 | Class III | Drugs | Lot # 21 P0322, Exp. 01/2023 | Subpotent | Jubilant Cadista Pharmaceuticals, Inc. |
| 23.4% Sodium Chloride Injection, 120 mEq per 30 mL (4 mEq/mL), 50 mL prefilled | Class III | Drugs | Lots: 210137-01 BUD: 05/25/2022; 220026-01 | Labeling: Incorrect Barcode: Product barcode incorrectly | The Ritedose Corporation |

| Product Description | Classification | Product Type | Code Info | Reason for recall | Recalling Firm |
|---|---|---|---|---|---|
| syring, Rx Only, RITEDOSE, 503B Outsourcing Facility, A Division of the RITEDOSE Corporation, 1 Technology Circle, Columbia, SC 29203, 1-866-994-4670, NDC: 65302-509-30, barcode N (01) 003 65302 50930 0 | | | BUD: 8/12/2022; 220050-01 BUD: 08/22/2022 | identifies the product as rocuronium bromide injection 100 mg per 10 mL instead of sodium chloride injection 23.4%, 120 mEq per 30 mL. | |
| Cyanocobalamin Injection, USP, 1,000 mcg per mL, For IM or SC Use Only, 1 mL Vial, Rx Only, Manufactured in India, for Auromedics Pharma LLC, NDC 55150-364-01. | Class III | Drugs | Lots: CCC210004, Exp 09/2022; CCC210005, CCC210006, CCC210007, Exp 11/2022; CCC210010, CCC210011, Exp 04/2023. | Subpotent Drug: Out of Specification results for Assay | Aurobindo Pharma USA Inc. |

*Please refer to FDA website for further information at: http://www.fda.gov/Safety/Recalls/default.htm

# FDA DRUG SAFETY COMMUNICATIONS

**[3/30/2022] FDA recommends thyroid monitoring in babies and young children who receive injections of iodine-containing contrast media for medical imaging**

*Children with underlying conditions and newborns at higher risk*

*This is an update to the FDA Drug Safety Communication: FDA advises of rare cases of underactive thyroid in infants given iodine-containing contrast agents for medical imaging issued on November 17, 2015.*

**What safety concern is FDA announcing?**
Based on our recent review of published studies, the U.S. Food and Drug Administration (FDA) is recommending that newborns and children through 3 years old have follow-up thyroid monitoring within 3 weeks after receiving injections of contrast media containing iodine, also called "contrast dye," for X-rays and other medical imaging procedures. Our review showed that underactive thyroid or a temporary decrease in thyroid hormone levels were uncommon. However, the conditions should be identified and treated early when needed to prevent potential future complications. Newborns, particularly those born premature, and children in their first 3 years with underlying conditions such as heart issues may be at higher risk for problems of the thyroid, a gland in the neck that releases hormones that help control many of the body's functions.

**What is FDA doing?**
We have approved a new warning to the prescribing information for the entire class of iodinated contrast media (ICM) injections and monitoring recommendations for children 3 years or younger. The warning describes the risk of underactive thyroid or a temporary decrease in thyroid hormone levels. These risks and recommendations pertain to ICM given as an injection through an artery or vein.

**What are ICM injections and how can they help my child?**
ICM have been approved for decades and are drugs containing iodine given to patients to enhance the ability to see blood vessels, organs, and tissues on medical images such as X-rays or computed tomography (CT) scans (see Table 1 below for a list of products). This results in detailed images that can help health care professionals diagnose potential problems.

**What should parents and caregivers do?**
Parents and caregivers should talk to your child's health care professional for additional information or if you have any questions or concerns about your child receiving an ICM injection. Babies and young children typically do not show any visible signs of thyroid problems and may need to be monitored by their health care professionals after receiving ICM.

**What should health care professionals do?**
Health care professionals should perform appropriate monitoring of patients from birth through 3 years for the possibility of hypothyroidism or a temporary decrease in thyroid hormone levels following exposure to ICM. Consider evaluating thyroid function within 3 weeks, especially in term and preterm neonates and children with some underlying conditions. If thyroid dysfunction is detected, treat and

monitor thyroid function as clinically needed to avoid future cognitive and other developmental disabilities.

Certain pediatric patients are at an increased risk, including those who are newborns or have very low birth weight, prematurity, or the presence of cardiac or other conditions such as those requiring care in neonatal or pediatric intensive care units. Patients with cardiac conditions may be at greatest risk since they often require high doses of contrast during invasive cardiac procedures.

**What did FDA find?**
Since 2015 when FDA first alerted the public about cases of underactive thyroid in infants receiving ICM, six new research studies evaluating this risk have been published.[1-6] We reviewed these six studies and the five earlier ones[7-11] published in the medical literature that assessed thyroid function in a range of 10 to 2,320 children from birth through 3 years who were exposed to ICM. Most cases of decreased thyroid hormone levels were temporary and did not require treatment. The reported rate ranged from 1 percent to 15 percent and tended to be higher in newborns, particularly those who were preterm. Patients with cardiac conditions were at greatest risk since they often require high doses of contrast during invasive cardiac procedures such as catheterization and CT. The time from ICM exposure to diagnosis ranged between 8.5 and 138 days, with most occurring within 3 weeks in some of the publications.

In 2015, we required the manufacturers of ICM products to conduct a study to investigate this safety issue further. However, we have concluded based on our review of the published studies[1-11] that there is compelling evidence of a significant risk for underactive thyroid or a temporary decrease in thyroid hormone levels in newborns and children through 3 years after exposure to ICM; therefore, the study by the manufacturers is no longer needed.

**What is my child's risk?**
All medicines have side effects, but when used correctly as prescribed, the benefits of taking a medicine outweigh these risks. It is important to know that people respond differently to all medicines depending on their health, other medicines they are taking, the diseases they have, genetic factors, and many other factors. As a result, we cannot determine how likely it is that your child will experience underactive thyroid or a temporary decrease in thyroid hormone levels after receiving ICM. However, if your child is a newborn, has very low birth weight, was premature, has a heart condition, or was admitted to a neonatal or pediatric intensive care unit, they may be at higher risk after receiving ICM.

**How do I report side effects from ICM?**
To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving ICM or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

**How can I get new safety information on medicines I'm prescribing or taking?**
You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

**Table 1. FDA Approved Iodinated Contrast Media Injections**

| Generic name | Brand name(s) |
|---|---|
| iodixanol | Visipaque 270, 320 |
| iohexol | Omnipaque 140, 180, 240, 300, 350 |
| iopamidol | Isovue-200, 250, 300, 370<br>Isovue-M 200, 300 |
| iopromide | Ultravist 300, 370 |
| iothalamate meglumine | Conray, Conray 43 |
| ioversol | Optiray 300, 320, 350 |

**Facts about Iodinated Contrast Media (ICM) Injections**

- Also known as “contrast dye” or “X-ray dye,” ICM injections are drugs containing iodine that are used to enhance the ability to see blood vessels, organs, and tissues during medical imaging procedures.
- Procedures that use ICM include X-rays of blood vessels, joints, and organs, and some computed tomography (CT) scans.
- ICM are given as injections into arteries, veins, or other body cavities; however, the information in this Drug Safety Communication pertains to ICM given as an injection through an artery or vein.
- Common side effects associated with ICM include flushing in the face, nausea or vomiting, mild itchiness, and skin rash.

**Additional Information for Parents and Caregivers**

- X-ray scans and other types of medical imaging are important to help health care professionals diagnose a variety of conditions, but special care is needed after babies and young children receive injections of contrast media containing iodine, also called “contrast dye” or iodinated contrast media (ICM).
- Therefore, FDA recommends that newborns and children through 3 years have appropriate thyroid monitoring by their health care professionals after receiving ICM injections. The thyroid is a gland in the neck that releases hormones that help control many of the body’s functions.
- Underactive thyroid or a temporary decrease in thyroid hormone levels are uncommon in babies and young children after receiving ICM; however, newborns, particularly those born prematurely, and children in the first 3 years with underlying conditions such as heart issues may be at a higher risk.
- Babies and young children typically do not show any visible signs of underactive thyroid or temporary decrease in thyroid hormone levels. These forms of thyroid dysfunction can be evaluated through blood testing.
- Talk to your child’s health care professional if your child has received or will receive an ICM injection, or you have questions or concerns about ICM.
- To help FDA track safety issues with medicines, report side effects from ICM or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

**Additional Information for Health Care Professionals**

- FDA recommends monitoring of pediatric patients from birth through 3 years for the possibility of hypothyroidism or a temporary decrease in thyroid hormone levels following exposure to iodinated contrast media (ICM). Consider evaluating thyroid function within 3 weeks, especially in term and

preterm neonates. If thyroid dysfunction is detected, treat and monitor thyroid function as clinically needed.

- Thyroid dysfunction characterized by hypothyroidism or a temporary decrease in thyroid hormone levels has been reported after single exposure and multiple exposures to ICM.
- Pediatric patients from birth through 3 years warrant closer monitoring to prevent an underactive thyroid during early life that may harm motor, hearing, and cognitive development and may require transient T4 replacement therapy.
- Certain pediatric patients are at an increased risk, including newborns and those having very low birth weight, prematurity, or the presence of cardiac or other conditions such as those requiring care in neonatal or pediatric intensive care units. Patients with cardiac conditions may be at greatest risk since they often require high doses of contrast during invasive cardiac procedures such as catheterization and computed tomography (CT).
- Counsel parents and caregivers about the risk of their child developing hypothyroidism or a temporary decrease in thyroid hormone levels after receiving ICM and inform them that follow-up monitoring may be performed.
- To help FDA track safety issues with medicines, report adverse events involving ICM or other medicines to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

**Data Summary**

Since 2015 when FDA first alerted the public about cases of underactive thyroid in infants receiving iodinated contrast media (ICM), several research studies evaluating this risk have been published.1-6 We reviewed these six studies and the five earlier ones7-11 published in the medical literature that assessed thyroid function in a total of 3,481 children from birth through 3 years who were exposed to ICM. Six studies were prospective and five were retrospective. Of the 11 studies, seven were conducted in the European Union, three in the United States, and one in Israel. Two studies, one in the United States and one in Israel, were larger studies with 2,320 and 843 children, respectively. Both monitored children exposed to ICM for onset of thyroid dysfunction within 1 year of exposure. The remaining nine studies included children who either had very low birth weight, a cardiac history, or were in intensive care unit.

Most reported cases were transient subclinical hypothyroidism and did not require treatment. The reported rate ranged from 1 percent to 15 percent and tended to be higher in neonates, particularly preterm neonates. Patients with cardiac conditions were at greatest risk since they often require high doses of contrast during invasive cardiac procedures such as catheterization and computed tomography (CT). The time from ICM exposure to diagnosis of thyroid dysfunction ranged between 8.5 and 138 days, with most occurring within 3 weeks in some of the publications.

References

1. Kubicki R, Grohmann J, Kunz KG, Stiller B, Schwab KO, van der Werf-Grohmann N. Frequency of thyroid dysfunction in pediatric patients with congenital heart disease exposed to iodinated contrast media - a long-term observational study. J Pediatr Endocrinol Metab 2020;33:1409-15.
2. Jick SS, Hedderson M, Xu F, Cheng Y, Palkowitsch P, Michel A. Iodinated contrast agents and risk of hypothyroidism in young children in the United States. Invest Radiol 2019;54:296-301.

3. Rosenberg V, Michel A, Chodick G, Cheng Y, Palkowitsch P, Koren G, Shalev V. Hypothyroidism in young children following exposure to iodinated contrast media: an observational study and a review of the literature. Pediatr Endocrinol Rev 2018;16:256-65.
4. Belloni E, Tentoni S, Puci MV, Avogliero F, Della Latta D, Storti S, Alberti B, Bottoni A, Bortolotto C, Fiorina I, Montomoli C, Chiappino D. Effect of iodinated contrast medium on thyroid function: a study in children undergoing cardiac computed tomography. Pediatr Radiol 2018;48:1417-22.
5. Thaker VV, Galler MF, Marshall AC, Almodovar MC, Hsu HW, Addis CJ, Feldman HA, Brown RS, Levine BS. Hypothyroidism in infants with congenital heart disease exposed to excess iodine. J Endocr Soc 2017;1:1067-78.
6. Dechant MJ, van der Werf-Grohmann N, Neumann E, Spiekerkoetter U, Stiller B, Grohmann J. Thyroidal response following iodine excess for cardiac catheterisation and intervention in early infancy. Int J Cardiol 2016;223:1014-8.
7. Dembinski J, Arpe V, Kroll M, Hieronimi G, Bartmann P. Thyroid function in very low birthweight infants after intravenous administration of the iodinated contrast medium iopromide. Arch Dis Child Fetal Neonatal Ed 2000;82:F215-7.
8. Parravicini E, Fontana C, Paterlini GL, Tagliabue P, Rovelli F, Leung K, Stark RI. Iodine, thyroid function, and very low birth weight infants. Pediatrics 1996;98(4 Pt 1):730-4.
9. Ares S, Pastor I, Quero J, Morreale de Escobar G. Thyroid complications, including overt hypothyroidism, related to the use of non-radiopaque silastic catheters for parenteral feeding in prematures requiring injection of small amounts of an iodinated contrast medium. Acta Paediatr 1995;84:579-81.
10. Bona G, Zaffaroni M, Defilippi C, Gallina MR, Mostert M. Effects of iopamidol on neonatal thyroid function. Eur J Radiol 1992;14:22-5.
11. l'Allemand D, Grüters A, Beyer P, Weber B. Iodine in contrast agents and skin disinfectants is the major cause for hypothyroidism in premature infants during intensive care. Horm Res 1987;28:42-9.

# CURRENT DRUG SHORTAGES

Below is the list of drugs listed by the FDA as currently in shortage. Please refer to the FDA website for more information at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

**Generic Name or Active Ingredient**

Acetazolamide Injection
Amifostine Injection
Amino Acids
Amoxapine Tablets
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets
Amphetamine Oral Suspension, Extended Release
Atropine Sulfate Injection
Azacitidine for Injection
Azithromycin (Azasite) Ophthalmic Solution 1%
Bacteriostatic 0.9% Sodium Chloride Injection
Bacteriostatic Water for Injection
Belatacept (Nulojix) Lyophilized Powder for Injection
Bumetanide Injection
Bupivacaine Hydrochloride and Epinephrine Injection
Bupivacaine Hydrochloride Injection
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Cefazolin Injection
Cefixime Oral Capsules
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Chlordiazepoxide Hydrochloride Capsules
Chloroprocaine Hydrochloride Injection
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container
Continuous Renal Replacement Therapy (CRRT) Solutions
Cortisone Acetate Tablets
Cyclopentolate Ophthalmic Solution
Cysteamine Hydrochloride Ophthalmic Solution
Cytarabine Injection
Dacarbazine Injection
Desmopressin Acetate Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Dextrose 10% Injection
Dextrose 25% Injection
Dextrose 5% Injection
Dextrose 50% Injection

Diflunisal Tablets
Digoxin Injection
Diltiazem Hydrochloride Injection
Disopyramide Phosphate (Norpace) Capsules
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution
Enalaprilat Injection
Epinephrine Injection, 0.1 mg/mL
Epinephrine Injection, Auto-Injector
Fentanyl Citrate (Sublimaze) Injection
Floxuridine for Injection
Fluvoxamine ER Capsules
Furosemide Injection
Gemifloxacin Mesylate (Factive) Tablets
Gentamicin Sulfate Injection
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Hydrocortisone Tablets
Hydromorphone Hydrochloride Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Imipenem and Cilastatin for Injection
Isoniazid Injection
Ketamine Injection
Ketoprofen Capsules
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection
Leuprolide Acetate Injection
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags
Lidocaine Hydrochloride (Xylocaine) Injection
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine
Lipid Injection
Lithium Oral Solution
Lorazepam Injection
Loxapine Capsules
Mannitol Injection
Mepivacaine Hydrochloride Injection
Methyldopa Tablets
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Injection
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nefazodone Hydrochloride Tablets
Nizatidine Capsules
Ondansetron Hydrochloride Injection

Paclitaxel Injection (protein-bound particles)
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Pentostatin Injection
Physostigmine Salicylate Injection
Potassium Acetate Injection
Potassium Chloride Concentrate Injection
Promethazine (Phenergan) Injection
Propofol Injectable Emulsion
Protamine Sulfate Injection
Rifampin Capsules
Rifampin Injection
Rifapentine Tablets
Ropivacaine Hydrochloride Injection
Sclerosol Intrapleural Aerosol
Semaglutide (WEGOVYÂ®) Injection
Sincalide (Kinevac) Lyophilized Powder for Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection Bags
Sodium Chloride 14.6% Injection
Sodium Chloride 23.4% Injection
Sodium Chloride Injection USP, 0.9% Vials and Syringes
Sodium Phosphates Injection
Sterile Water for Injection
Streptozocin Powder for Injection
Sulfasalazine Tablets
Tacrolimus Capsules
Technetium Tc 99m Sulfur Colloid Injection
Technetium TC-99M Mebrofenin Injection
Technetium Tc99m Succimer Injection (DMSA)
Teprotumumab-trbw
Thiothixene Capsules
Triamcinolone Acetonide Injectable Suspension
Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Varenicline Tartrate (Chantix) Tablets
Vecuronium Bromide for Injection