| Drug | Recall Details | Contact | Date | Drug Recall Class* |
|--|---|--|--------------|--------------------|
| OTC eye drops by Harvard Drug Group, Rugby brand Polyvinyl alcohol, 1.4% lubricating eye drops: 0536-1325-94 Lubricating tears eye drops(dextran/Hypromellose 0.1%/0.3%): 0536-1282-94 | May be contaminated with bacteria. | If you have questions about this recall, call Sedgwick (appointed company for Harvard Drug Group) by phone at 866-891-1981 or by email at harvarddrug8430@sedgwick.com | October 2023 | Class II |
| OTC eye drops by Leader Eye Irritation Relief (polyvinyl alcohol/ 0.5%/povidone, 0.6%/ tetrahydrozoline hydrochloride, 0.05%):70000-0087-1 Dry Eye Relief (carboxymethylcellulose sodium, 1%): 70000-0089-1 Lubricant Eye Drops (carboxymethylcellulose sodium, 0.5%):70000-0090-1 Dry Eye Relief (polyethylene glycol 400, 0.4% and propylene glycol, 0.3%):70000-0088-1 Lubricant Eye Drops (propylene glycol, 0.6%): 70000-0587-1 | May be contaminated with bacteria. | If you have questions about this recall, call Sedgwick (appointed company for Cardinal) by phone at 855-215-4940 or by email at Cardinalhealth7720@sedgwick.c om | October 2023 | Class II |
| Sodium bicarbonate 8.4% inj Exela brand: 51754-5001-5 Civica brand: 72572-740-20 | Multiple lot recall because of particulate matter identified as silicone. Silicone particulate may cause local irritation/swelling. | If you have questions about this recall, call Exela by phone at 828-341-6118 or by email at recall@excel.us | October 2023 | Class II |
| Midazolam 0.8% inj 100mg/100 ml SDV Carton: 51754-2131-4; Vial: 51754-2131-1; Lot # 10001088 | One lot recall because of particulate matter identified as silicone. Silicone particulate may cause local irritation/swelling. | If you have questions about this recall, call Exela by phone at 828-341-6118 or by email at recall@excel.us | October 2023 | Class II |
| ELCYS (cysteine hydrochloride) inj Carton: 51754-1007-3; Vial: 51754-1007-1 Lot # 10000798 | One lot recall because of particulate matter identified as silicone. Silicone particulate may cause local irritation/swelling. | If you have questions about this recall, call Exela by phone at 828-341-6118 or by email at recall@excel.us | October 2023 | Class II |

| Sodium bicarbonate 4.2% inj | One lot recall because of | If you have questions about this | October 2023 | Class II |
|-----------------------------|-----------------------------------|-----------------------------------|--------------|----------|
| Carton: 0409-5534-24 | potential for presence of glass | recall, call Pfizer by | | |
| Case: 0409-5534-14 | particulate matter. Glass | phone at 800-438-1985, option 1 | | |
| | particulate may cause | or 3 or visit | | |
| | occlusion or injury if injected. | www.pfizermedinfo.com | | |
| Lidocaine hydrochloride 1% | Potential for presence of glass | If you have questions about this | October 2023 | Class II |
| and 2% inj | particulate matter. Glass | recall, call Pfizer by | | |
| Carton: 0409-4904-11& 0409- | particulate may cause | phone at 800-438-1985, option 1 | | |
| 4903-11 | occlusion or injury if injected. | or 3 or visit | | |
| Case: 0409-4904-34 | | www.pfizermedinfo.com | | |
| Sucralfate Oral suspension | One lot recall because of | If you have questions about this | September | Class II |
| 66689-305-16 | potential Bacillus cereus | recall, call VistaPharm by phone | 2023 | |
| Lot # 810300 | contamination. | at 800-967-5952 or by email at | | |
| | | rxrecalls@Inmar.com | | |
| Sandimmune (cyclosporine) | One lot recall because of | If you have questions about this | September | Class II |
| oral solution 100 mg/mL | crystal formation observed in | recall, call Novartis at 888-669- | 2023 | |
| 0078-0110-22 | some bottles, which could | 6682 | | |
| Lot # FX001691 | potentially result in incorrect | | | |
| | dosing. | | | |
| Brexafemme (ibrexafungerp) | Potential cross contamination | If you have questions about this | September | Class II |
| tablets | with a non-antibacterial beta- | recall, call Scynexis by phone at | 2023 | |
| 75788-115-04 | lactam drug substance in the | 877-551-7154 | | |
| | ibrexafungerp citrate used to | | | |
| | manufacture the Brexafemme | | | |
| | tablets. Potential cross | | | |
| | contamination could lead to | | | |
| | serious hypersensitivity | | | |
| | reactions. | | | |
| Betaxolol 10 mg tablets | One lot recall because of the | If you have questions about this | September | Class II |
| 10702-0013-01 | presence of a single foreign | recall, call KVK Tech by phone at | 2023 | |
| Lot # 17853A | tablet found during the | 215-579-1842, ext. 6002 or by | | |
| | manufacturer's packaging | email at | | |
| | process | customerservice@kvktech.com | | |
| 0.9% sodium chloride | One lot recall because part of | If you have questions about this | August 2023 | Class II |
| injection in EXCEL plus IV | the label is missing or partially | recall, call B. Braun Medical by | | |
| container (1000 mL) | printed: description, warnings, | phone at 833-425-1464 | | |

| 0264-5802-00 Lot # 0061852531 | storage information and instructions for use were either missing or partially printed. | | | |
|--|---|---|-------------|----------------------|
| Digoxin 0.125 mg and 0.25 mg tablets 10135-0747-01 (0.125 mg tablets) Lot # E3810 10135-0748-01 (0.25 mg tablets) Lot # E3811 | One lot recalls because the bottles are mislabeled and contain the wrong strength of medication. | If you have questions about this recall, call Marlex at 302-328-3355 or at 888-582-1953 | August 2023 | Class II |
| 0.9% sodium chloride injection in EXCEL plus IV container (1000 mL) 0264-5802-00 | Possibility of an incomplete seal that may cause the product to leak. Sterility may be compromised. | If you have questions about this recall, call B. Braun Medical by phone at 833-425-1464 | July 2023 | Class II |
| Tydemy (drospirenone/ethinyl estradiol and levomefolate calcium) 68180-904-71 68180-904-73 | Manufacturing test results showed a significant reduction in the amount of inactive content that could potentially impact the effectiveness of contraception provided by the medication, which may result in an unexpected pregnancy. | If you have questions about this recall, call Inmar at 866-480-8206 | July 2023 | Class II |
| Cromolyn oral solution 100 mg/5 mL 76204-025-96 | Manufacturing issues related to an alternative source of drug. Product was manufactured and released for dispensing prior to final FDA approval. | If you have questions about this recall, call Ritedose at 803-806-3300 | July 2023 | Class II |
| Albuterol sulfate inhalation aerosol, 90 mcg (200 metered inhalation) 69097-142-60 | Inhalation aerosol may leak and not administer the correct amount of medicine. | If you have questions about this recall, call Cipla at 844-247-5287 or by email at cipla.cs@cipla.com | July 2023 | Class II |
| Oxandrin (brand and generic: oxandrolone) | Potential problems associated with oxandrolone tablets are sufficiently serious that the drug | To review the FDA information related to this withdrawal, please visit | June 2023 | Market Withdrawal |

| | products should be removed from the market. Multiple serious health effects including: liver issues, blood lipid changes associated with atherosclerosis, hypercalcemia in patients with breast cancer, risk of prostatic hypertrophy, and risk of prostatic carcinoma in geriatric patients | https://www.regulations.gov/doc ument/FDA-2023-N-2226-0001 | | |
|--|--|--|------------|----------------------|
| Dronabinol and Ziprasidone capsules 0904-7144-61 (dronabinol) Lot # T04769 0904-6269-08 (ziprasidone) Lot # T04769 | One lot recall of dronabinol capsules and one lot of ziprasidone capsules because some cartons labeled as ziprasidone were found to contain blister packages labeled as and containing dronabinol. Both products are being recalled out of an abundance of caution. | If you have questions about this recall, call Sedgwick (appointed company for Major) at 888-759-6904 or by email at harvarddrug6068@sedgwick.com | June 2023 | Class II |
| Contour Next Gen Glucose Meters 90002902 (SKU 7919) Lot # DM01T033P | One lot recall because of incorrect factory-set units of measurement where the meters display glucose results in mmol/L rather than mg/dL. | If you have questions about this recall, call Ascensia at 800-348-8100 or by email at support@ContourNext.com | June 2023 | Class II |
| Injectable antibiotic products <u>List of affected medications</u> <u>linked here</u> | Quality concerns identified at manufacturing facility and the sterility of these products cannot be assured. | If you have questions about this recall, call Sedgwick at 888-719-5826 | May 2023 | Class II |
| Makena (brand and generic: hydroxyprogesterone caproate) | Benefits do not outweigh their risk. Confirmatory clinical trial failed to demonstrate effectiveness in reducing the risk of preterm birth in any group. | More information can be found in FDA's Final Decision on the Proposal to Withdraw Approval of Makena and related materials, available at: https://www.fda.gov/drugs/postmarket-drug-safety-information- | April 2023 | Market Withdrawal |

| Fyremadel (ganirelix acetate) injection, 250 mcg/0.5 mL 55566-1010-1 Lot # HAD1190A | One lot recall because of glass particles observed in a prefilled syringe. | patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information. If you have questions about this recall, call Sun Pharma by phone at 800-406-7984 or by email at drug.safetyUSA@sunpharma.co | April 2023 | Class II |
|--|---|--|------------|----------|
| Freestyle Libre CGM Reader Devices | Batteries may get extremely hot, spark, or catch on fire if not properly stored, charged, or used with its Abbott provided USB cable and power adapter; sensors are unaffected. | If you have questions about this recall, call Abbott at 855-632-8658 or online www.freestylebattery.com | April 2023 | Class II |
| Fentanyl buccal tablets 51862-634-28 51862-635-28 51862-636-28 51862-637-28 51862-638-28 | Safety updates were omitted in the Product Insert/Medication Guide that are provided with the recalled lots. | If you have questions about this recall, call Teva by phone at 888-483-8279 or by email at USMedInfo@tevapharma.com for more information. *For instructions on how to return the recalled fentanyl, contact Inmar by phone at 855-246-5024 or by email at rxrecalls@inmar.com. | April 2023 | Class II |
| Akorn, manufacturer of generic medication products <u>Full list of affected</u> <u>medications linked here</u> | Manufacturer declared bankruptcy, cannot support ongoing quality monitoring of products, ceasing all operations. | If you have questions about this recall, call Akorn at 800-932-5676 | April 2023 | Class II |
| Nurtec ODT 75mg 8-unit dose blister pack 72618-3000-2 | Tablets are in a non-child resistant blister card. | If you have questions about this recall, call Pfizer at 800-879-3477 or online www.Nurtec.com/PackagingUpda te to obtain free child-resistant, resealable pouches | March 2023 | Class II |

| Lidocaine/prilocaine 2.5%/2.5% cream 0168-0357-56 (carton) 0168-0357-55 (carton) 0168-0357-05 (tube) | Packaging is not child-resistant, posing a risk of harm if children put the cream on their skin. | If you have questions about this recall, call Sandoz at 866-300-2207 to obtain free child-resistant, resealable pouches to store the recalled drugs. You can also call Sandoz at 800-525-8747 for more information about the recall. | March 2023 | Class II |
|--|---|--|---------------|----------|
| Dabigatran 75 mg and 150 mg capsules 67877-474-60 67877-475-60 | Contamination with N- nitroso-dabigatran, a potential carcinogen. | If you have questions about this recall, call Ascend at 877- 272-7901 | March 2023 | Class II |
| Brimonidine tartrate ophthalmic solution 0.15% 60505-0564-1 60505-0564-2 60505-0564-3 | Cracks have developed in some of the caps of the bottles that may impact sterility. | If you have questions about this recall, call Inmar by phone at 800-706-5575 or by e-mail at UScustomerservice@Apotex.com for more information. | March 2023 | Class II |
| Atovaquone oral suspension, 750 mg/5 mL 31722-629-21 | One lot recall because of potential <i>Bacillus cereus</i> contamination in the product. | If you have questions about this recall, call Camber by phone at 877-597-0878 or by email at rxrecalls@inmar.com | March 2023 | Class II |
| Aprepitant 125 mg capsules 0781-2323-06 (blister pack) 0781-2323-68 (carton) | Packaging is not child-resistant, posing a risk of harm if children ingest the drug. | If you have questions about this recall, call Sandoz at 866-300-2207 to obtain free child-resistant, resealable pouches to store the recalled drugs. You can also call Sandoz at 800-525-8747 for more information about the recall. | March 2023 | Class II |
| 0.9% sodium chloride injection in EXCEL plus IV container (500 mL and 1000 mL) 00264-5802-10 00264-5802-00 | Possibility of an incomplete seal that may cause the product to leak. Sterility may be compromised. | If you have questions about this recall, call B. Braun Medical by phone at 833-425-1464 or by email at ProductQualityExcellence@bbraunusa.com | February 2023 | Class II |

| Heparin sodium injection, 20,000 USP units per mL 25021-404-01 | One lot recall due to mislabeling on the back panel of the carton the vial is packaged in. The incorrect labeling omits the preservative and states the incorrect concentration. | If you have questions about this recall, call Sagent Pharma at 866-625-1618 | February 2023 | Class II |
|--|--|--|---------------|----------|
| BD Insulin Syringes with the BD Micro-Fine IV Needle 1 mL, 12.7 mm, 28 G | Manufacturing issues that can result in unsealed packaging for the individual syringes. Unsealed syringes may no longer be sterile. | If you have questions about this recall, call BD by phone at 844-823-5433 or by email at productcomplaints@bd.com | February 2023 | Class II |
| Artificial Eye Ointment (mineral oil 15%, white petrolatum 83%) 3.5 grams (1/8 oz.) 72570-122-35 | Possible contamination with bacteria. Additionally, the tubes may leak, compromising sterility. Use of contaminated product may lead to eye infections that could result in blindness. | If you have questions about this recall, call Delsam Pharma by phone at 866-826-1306 or by email at delsampharma@yahoo.com | February 2023 | Class II |
| Artificial Tears 79503-0101-15- Ezricare Artificial Tears 72570-121-15 - Delsam Pharma's Artificial Tears | Possible contamination with extensively drug-resistant Pseudomonas aeruginosa; use of contaminated artificial tears may lead to eye infections that could result in blindness. | If you have questions about this recall, call Aru Pharma/Ezricare by phone at 516-715-5181 or by e-mail at arupharmainc@yahoo.com OR you can contact Delsam Pharma by phone at 866-826-1306 or by e-mail at delsampharma@yahoo.com | February 2023 | Class II |
| Tirosint-Sol (levothyroxine oral solution) 71858-0105-5 71858-0110-5 71858-0112-5 71858-0113-5 71858-0115-5 71858-0117-5 | Some lots may be subpotent; this does <i>not</i> affect Tirosint <i>capsules</i> | If you have questions about this recall, call IBSA Pharma by phone at 800-587-3513 or by email at medinfo@ibsapharma.com | January 2023 | Class II |

| 71858-0120-5 71858-0125-5 71858-0130-5 71858-0135-5 71858-0140-5 71858-0145-5 71858-0150-5 71858-0150-5 71858-0160-5 | | | | |
|--|--|---|--------------|----------|
| Ferrous sulfate 324 mg tablets 69375-0003-10 | Lack of child safety caps on the manufacturer bottles. | If you have questions about this recall, call Nationwide Pharmaceutical by phone at 800-697-3329 or by e-mail at recalls@nwp-mail.com | January 2023 | Class II |

Legend: the number immediately beneath the product name is the NDC(s) of the affected product(s)

Class 1 Recall: Reasonable probability that using the drug will cause serious adverse health consequences or death.

Class 2 Recall: Using the drug may cause temporary or medical reversible adverse health consequences, the probability of serious adverse health consequences is remote.

Class 3 Recall: Using the drug is not likely to cause adverse health consequences.

NOTE: This is not a complete list of all recalls. Please see FDA.gov >Drugs>Drug Safety and Availability> Drug Recalls for additional information.

^{*} Drug Recall Class