

June 06, 2019

## Urgent: Torrent Pharma, Inc. Issues a Voluntary Recall of Multiple Lots of Affected OTC Products

Dear ASD Healthcare Customer:

Torrent Pharma, Inc. is initiating a voluntary recall of multiple lots of over-the-counter (OTC) products sold under the Major and Rugby distributor labels. The affected lot information is listed in the attached document.

These products are being voluntarily recalled due to potential product contamination with *Burkholderia cepacia* (*B. cepacia*) and *Ralstonia pickettii* (*R. pickettii*). Torrent Pharma, Inc. is requesting that the use of these lots and products be immediately discontinued and the product returned to the company.

**Torrent Pharma, Inc. provided the affected lot information on the following pages.** Please note that returns are only limited to the listed.

**To reduce any risk, we ask for your cooperation in taking the following action:**

- **Please examine your inventory immediately to determine if you have any impacted product in stock.**
- **If you do have inventory of any of the recalled lot numbers, please stop distribution and dispensing of the product and quarantine impacted units.**
- **Please complete the attached Business Response Form to begin the return process.** A paid return label and further return directions will then be provided. If the product you are returning is DEA schedule IV or V controlled substance, please ensure you provide your DEA registration number on this form.
- Arrange for product to be returned to:  
Qualanex, LLC.  
1410 Harris Road  
Libertyville, IL 60048

**For the full recall notice, please view the attached document on the following pages.**

If you have any questions or concerns, please contact ASD Healthcare's customer service at **800.746.6273**.

## URGENT DRUG PRODUCT SUB RECALL

### Date June 3, 2019

Dear Valued Customer:

Torrent Pharma, Inc. initiated a voluntary recall on May 21, 2019, to the retail level, for all products and lots listed below. Torrent Pharma, Inc. is recalling all products, within expiry, manufactured at its Levittown, PA facility due to potential product contamination with *Burkholderia cepacia* (*B.cepacia*) and *Ralstonia pickettii* (*R. pickettii*).

Pharmaceutical products that are contaminated with *B.cepacia* and *R. pickettii* may pose potential risk to vulnerable patients (e.g., immunocompromised patients) and/or patients with cystic fibrosis and persons with decreased immunity such as neonates, infants and the elderly. Some of these infections may be serious or even life threatening in the at-risk patient population.

To date, Torrent Pharma, Inc. has not received any reports of adverse events related to this recall.

This recall includes over the counter (OTC) drug products sold under the Major and Rugby distributor labels. This recall is being executed with the knowledge of the Food and Drug Administration.

The products and lots included in the recall are listed below.

NDC No	Product Name	Label	Lot	Expiration
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	18E004	05/2020
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	18E032	05/2020
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	17E036	05/2019
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	17F008	06/2019
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	17F008A	06/2019
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	17H030	08/2019
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	17K017	10/2019
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	17L017	11/2019
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	17M031	12/2019
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	18A020	01/2020
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	18A040	01/2020
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	18B036	02/2020
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	18C032	03/2020
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	18F001	06/2020
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	18H006	08/2020
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	18K032	10/2020
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	18L003	11/2020
0536-0122-85	Pain & Fever Oral Solution (Acetaminophen, 160 mg/5 mL), 16 oz	Rugby	19A007	01/2021
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18E009	05/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18E019	05/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17E022	05/2019
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18E028	05/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17E037	05/2019
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17G006	07/2019
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17G026	07/2019
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17H019	08/2019
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17H020	08/2019

NDC No	Product Name	Label	Lot	Expiration
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17J020	09/2019
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17K006	10/2019
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17K012	10/2019
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17L028	11/2019
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	17L033	11/2019
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18A001	01/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18A006	01/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18A013	01/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18A038	01/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18B036	02/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18C024	03/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18F010	06/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18H003	08/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18J010	09/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18J012	09/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18J013	09/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18J019	09/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18K003	10/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	18K012	10/2020
0536-0122-97	Pain & Fever (Acetaminophen Oral Solution) 160 mg/5 mL, 4 oz	Rugby	19A016	01/2021
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	17E010	05/2019
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP) 12.5 mg/5 mL, 16 oz	Rugby	18E011	05/2020
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	17E030	05/2019
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	17F010	07/2019
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	17F013	06/2019
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	17J014	09/2019
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	17L005	11/2019
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	17M017	12/2019
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	18A022	01/2020
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	18B021	02/2020
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	18D017	04/2020
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	18F041	06/2020
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	18G021	08/2020
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	18H022	08/2020
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	18H028	08/2020
0536-0770-85	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 16 oz	Rugby	18H030	08/2020
0536-0770-97	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 4 oz	Rugby	18E011	05/2020
0536-0770-97	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 4 oz	Rugby	17H025	08/2019
0536-0770-97	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 4 oz	Rugby	17M022	12/2019
0536-0770-97	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 4 oz	Rugby	18G018	07/2020
0536-0770-97	Diphenhist Oral Solution (Diphenhydramine HCl, USP), 12.5 mg/5 mL, 4 oz	Rugby	18J014	09/2020
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	17F022	06/2019
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	17G027	07/2019
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	17H021	08/2019
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	17H021A	08/2019
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	17J008	09/2019
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	17L001	11/2019
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	17M015	12/2019
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18A018	01/2020
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18B003	02/2020
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18B008	02/2020
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18C012	03/2020
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18D005	04/2020
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18F008	06/2020

NDC No	Product Name	Label	Lot	Expiration
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18F043	06/2020
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18G025	07/2020
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18H004	07/2020
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18H007	08/2020
0536-0825-85	Cough Syrup (Guaifenesin Syrup, USP) 200 mg/10 mL, 16 oz	Rugby	18H016	08/2020
0536-0970-85	Extra Action Cough Syrup (Guaifenesin and Dextromethorphan HBr Syrup) 100 mg/10 mg per 5 mL, 16 oz	Rugby	18E008	05/2020
0536-0970-85	Extra Action Cough Syrup (Guaifenesin and Dextromethorphan HBr Syrup) 100 mg/10 mg per 5 mL, 16 oz	Rugby	17L023	11/2019
0536-0970-85	Extra Action Cough Syrup (Guaifenesin and Dextromethorphan HBr Syrup) 100 mg/10 mg per 5 mL, 16 oz	Rugby	17M027	12/2019
0536-0970-85	Extra Action Cough Syrup (Guaifenesin and Dextromethorphan HBr Syrup) 100 mg/10 mg per 5 mL, 16 oz	Rugby	17M027A	12/2019
0536-0970-85	Extra Action Cough Syrup (Guaifenesin and Dextromethorphan HBr Syrup) 100 mg/10 mg per 5 mL, 16 oz	Rugby	18A024	01/2020
0536-0970-85	Extra Action Cough Syrup (Guaifenesin and Dextromethorphan HBr Syrup) 100 mg/10 mg per 5 mL, 16 oz	Rugby	18B029	02/2020
0536-0970-85	Extra Action Cough Syrup (Guaifenesin and Dextromethorphan HBr Syrup) 100 mg/10 mg per 5 mL, 16 oz	Rugby	18C018	03/2020
0536-0970-97	Extra Action Cough Syrup (Guaifenesin and Dextromethorphan HBr Syrup) 100 mg/10 mg per 5 mL, 4 oz	Rugby	17E034	05/2019
0536-0970-97	Extra Action Cough Syrup (Guaifenesin and Dextromethorphan HBr Syrup) 100 mg/10 mg per 5 mL, 4 oz	Rugby	18C021	03/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	18E005	05/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	18E025	05/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	17G004	07/2019
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	17G028	07/2019
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	18A034	01/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	18C016	03/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	18D033	04/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	18F038	06/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	18G015	07/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	18H024	08/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	18K024	10/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	18L011	11/2020
0536-1355-01	Laxative Suppositories (Bisacodyl USP, 10 mg), 100's	Rugby	19A009	01/2021
0536-1355-12	Laxative Suppositories (Bisacodyl USP, 10 mg), 12's	Rugby	17K009	10/2019
0536-1355-12	Laxative Suppositories (Bisacodyl USP, 10 mg), 12's	Rugby	17M028	12/2019
0536-1355-12	Laxative Suppositories (Bisacodyl USP, 10 mg), 12's	Rugby	18F003	06/2020
0536-1355-12	Laxative Suppositories (Bisacodyl USP, 10 mg), 12's	Rugby	18J022	09/2020
0536-1355-12	Laxative Suppositories (Bisacodyl USP, 10 mg), 12's	Rugby	18L012	11/2020
0536-1355-12	Laxative Suppositories (Bisacodyl USP, 10 mg), 12's	Rugby	19A008	01/2021
0536-1389-12	Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Rugby	17L008	05/2019
0536-1389-12	Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Rugby	17M019	06/2019
0536-1389-12	Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Rugby	17M037	06/2019
0536-1389-12	Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Rugby	18B012	08/2019
0536-1389-12	Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Rugby	18B023	08/2019
0536-1389-12	Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Rugby	18K023	04/2020

NDC No	Product Name	Label	Lot	Expiration
0536-1850-85	Pseudoephedrine HCL Oral solution, 30 mg/5 mL, 16 oz	Rugby	17H012	08/2019
0536-1850-85	Pseudoephedrine HCL Oral solution, 30 mg/5 mL, 16 oz	Rugby	17L011	11/2019
0536-1850-85	Pseudoephedrine HCL Oral solution, 30 mg/5 mL, 16 oz	Rugby	17M020	12/2019
0536-1850-85	Pseudoephedrine HCL Oral solution, 30 mg/5 mL, 16 oz	Rugby	18D007	04/2020
0536-1850-85	Pseudoephedrine HCL Oral solution, 30 mg/5 mL, 16 oz	Rugby	18J001	09/2020
0536-1850-97	Nasal Decongestant Liquid (Pseudoephedrine HCl, 30 mg/5 mL), 4 oz	Rugby	17G002	07/2019
0536-1850-97	Nasal Decongestant Liquid (Pseudoephedrine HCl, 30 mg/5 mL), 4 oz	Rugby	17H024	08/2019
0536-1850-97	Nasal Decongestant Liquid (Pseudoephedrine HCl, 30 mg/5 mL), 4 oz	Rugby	17M023	12/2019
0536-1850-97	Nasal Decongestant Liquid (Pseudoephedrine HCl, 30 mg/5 mL), 4 oz	Rugby	18F012	06/2020
0536-2310-97	Kid Kare Children's Cough/Cold Liquid (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Rugby	17E009	05/2019
0536-2310-97	Kid Kare Children's Cough/Cold Liquid (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Rugby	17L004	11/2019
0536-2310-97	Kid Kare Children's Cough/Cold Liquid (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Rugby	17L004A	11/2019
0536-2310-97	Kid Kare Children's Cough/Cold Liquid (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Rugby	17L020	11/2019
0536-2310-97	Kid Kare Children's Cough/Cold Liquid (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Rugby	17M029	12/2019
0536-2310-97	Kid Kare Children's Cough/Cold Liquid (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Rugby	18C010	03/2020
0536-2310-97	Kid Kare Children's Cough/Cold Liquid (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Rugby	18C025	03/2020
0536-2310-97	Kid Kare Children's Cough/Cold Liquid (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Rugby	18J020	09/2020
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	18E020	05/2020
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	17F001	06/2019
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	17G016	07/2019
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	17H017	08/2019
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	17L002	11/2019
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	17L024	11/2019
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	17M010	12/2019
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	17M013	12/2019
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	18B006	02/2020
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	18B031	02/2020
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	18C033	03/2020

NDC No	Product Name	Label	Lot	Expiration
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	18D015	04/2020
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	18D016	04/2020
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	18G013	07/2020
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	18L010	11/2020
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	19A010	01/2021
0904-0053-00	Robafen DM Cough Formula (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 4 oz	Major	19A019	01/2021
0904-0053-09	Robafen DM Cough (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 8 oz	Major	18E026	05/2020
0904-0053-09	Robafen DM Cough (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 8 oz	Major	17F015	06/2019
0904-0053-09	Robafen DM Cough (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 8 oz	Major	17L009	11/2019
0904-0053-09	Robafen DM Cough (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 8 oz	Major	17M012	12/2019
0904-0053-09	Robafen DM Cough (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 8 oz	Major	18B015	02/2020
0904-0053-09	Robafen DM Cough (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 8 oz	Major	18C021	03/2020
0904-0053-09	Robafen DM Cough (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 8 oz	Major	18C034	03/2020
0904-0053-09	Robafen DM Cough (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 8 oz	Major	18G011	08/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	17E014	05/2019
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18E018	05/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	17G009	07/2019
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	17G020	07/2019
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	17K019	10/2019
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	17L012	11/2019
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	17L013	11/2019
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	17M016	12/2019
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	17M033	12/2019
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18A002	01/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18B009	02/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18B019	02/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18C015	03/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18C035	03/2020

NDC No	Product Name	Label	Lot	Expiration
	Guaifenesin, USP 200 mg/10 mL), 16 oz			
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18D001	04/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18D002	04/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18F027	06/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18H017	08/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18H018	08/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18K016	10/2020
0904-0053-16	Robafen DM Syrup (Dextromethorphan HBr, USP 20 mg/10 mL and Guaifenesin, USP 200 mg/10 mL), 16 oz	Major	18K035	10/2020
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	17F003	06/2019
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	17J011	09/2019
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	17K018	10/2019
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	17K020	10/2019
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	17M014	12/2019
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	17M034	12/2019
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	18A035	01/2020
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	18B022	02/2020
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	18B027	02/2020
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	18C036	03/2020
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	18D009	04/2020
0904-0061-00	Robafen Cough Formula Expectorant (Guaifenesin USP 200 mg/10 mL), 4 oz	Major	18D024	04/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18E017	05/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	17G018	07/2019
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	17H001	08/2019
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	17H010	08/2019
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	17H014	08/2019
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	17J009	09/2019
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	17K023	10/2019
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	17L006	11/2019
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	17L025	11/2019
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	17M025	12/2019
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	17M034	12/2019
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18A005	01/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18A012	01/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18A016	01/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18B020	02/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18C023	03/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18C031	03/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18G005	07/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18G022	07/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18H021	08/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18H026	08/2020
0904-0061-16	Robafen Syrup (Guaifenesin Syrup USP 200 mg/10 mL), 16 oz	Major	18J003	09/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl) Oral Solution, USP, 12.5 mg/5 mL, 4 oz	Major	18E014	05/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17E018	05/2019
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17E020	05/2019

NDC No	Product Name	Label	Lot	Expiration
	mL, 4 oz			
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17E026	05/2019
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17H008	08/2019
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17H018	08/2019
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17H028	08/2019
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17J002	09/2019
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17J025	09/2019
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17J028	09/2019
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17L035	11/2019
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	17M024	12/2019
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	18A017	01/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	18B016	02/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	18C011	03/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl) Oral Solution, USP, 12.5 mg/5 mL, 4 oz	Major	18D014	04/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl) Oral Solution, USP, 12.5 mg/5 mL, 4 oz	Major	18D021	04/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl) Oral Solution, USP, 12.5 mg/5 mL, 4 oz	Major	18D026	04/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	18F035	07/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	18F036	06/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	18G018	07/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	18H005	08/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	18H015	08/2020
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	19A011	01/2021
0904-1228-00	Banophen Allergy (Diphenhydramine HCl Oral Solution, USP), 12.5 mg/5 mL, 4 oz	Major	19A013	01/2021
0904-1985-00	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Unboxed)	Major	17E003	05/2019
0904-1985-00	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Unboxed)	Major	18E027	05/2020
0904-1985-00	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Unboxed)	Major	18E033	05/2020
0904-1985-00	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Unboxed)	Major	17E038	05/2019
0904-1985-00	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Unboxed)	Major	17F002	06/2019
0904-1985-00	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Unboxed)	Major	17F005	06/2019
0904-1985-00	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Unboxed)	Major	17F007	06/2019
0904-1985-00	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Unboxed)	Major	17F025	06/2019
0904-1985-00	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Unboxed)	Major	17G014	07/2019
0904-1985-00	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Unboxed)	Major	17H015	08/2019





NDC No	Product Name	Label	Lot	Expiration
0904-1985-16	Mapap Liquid (Acetaminophen USP, 160 mg/5 mL), 16 oz	Major	18G019	07/2020
0904-1985-16	Mapap Liquid (Acetaminophen USP, 160 mg/5 mL), 16 oz	Major	18H006	08/2020
0904-1985-16	Mapap Liquid (Acetaminophen USP, 160 mg/5 mL), 16 oz	Major	18H008	06/2020
0904-1985-16	Mapap Liquid (Acetaminophen USP, 160 mg/5 mL), 16 oz	Major	18H009	08/2020
0904-1985-16	Mapap Liquid (Acetaminophen USP, 160 mg/5 mL), 16 oz	Major	18H025	08/2020
0904-1985-16	Mapap Liquid (Acetaminophen USP, 160 mg/5 mL), 16 oz	Major	19A002	01/2021
0904-1985-20	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Boxed)	Major	17E003	05/2019
0904-1985-20	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Boxed)	Major	17F025	06/2019
0904-1985-20	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Boxed)	Major	17J006	09/2019
0904-1985-20	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Boxed)	Major	17K021	10/2019
0904-1985-20	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Boxed)	Major	18A039	01/2020
0904-1985-20	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Boxed)	Major	18C026	03/2020
0904-1985-20	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Boxed)	Major	18F033	06/2020
0904-1985-20	Children's Mapap Acetaminophen Liquid, 160 mg/5 mL, 4 oz (Boxed)	Major	18J008	09/2020
0904-5050-20	Pedia-Relief Cough-Cold Oral Solution (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Major	17L020	11/2019
0904-5050-20	Pedia-Relief Cough-Cold Oral Solution (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Major	18C025	03/2020
0904-5050-20	Pedia-Relief Cough-Cold Oral Solution (Chlorpheniramine Maleate, USP 1 mg/5 mL; Dextromethorphan HBr, USP 5 mg/5 mL; Pseudoephedrine HCl, USP 15 mg/5 mL), 4 oz	Major	18J020	09/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18E002	05/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	17E004	05/2019
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	17E033	05/2019
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	17F019	06/2019
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	17G017	07/2019
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	17K009	10/2019
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	17K030	10/2019
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	17M006	12/2019
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	17M028	12/2019
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18A029	01/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18C037	03/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18F003	06/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18F013	06/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18G002	07/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18G016	07/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18H031	08/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18J004	09/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18L008	11/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	18L012	11/2020
0904-5058-12	Biscolax Laxative (Bisacodyl, USP 10 mg), 12's	Major	19A008	01/2021
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	17E005	05/2019
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	18E025	05/2020
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	17E027	05/2019
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	17K025	10/2019
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	17M006	12/2019
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	18A014	01/2020
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	18B039	02/2020
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	18C037	03/2020
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	18D033	04/2020
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	18F013	06/2020
0904-5058-60	Biscolax Laxative (Bisacodyl, USP 10 mg), 100's	Major	18F018	06/2020



NDC No	Product Name	Label	Lot	Expiration
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	17E011	05/2019
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	17E012	06/2019
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	17G019	07/2019
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	17G023	07/2019
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	17H011	08/2019
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	17J029	09/2019
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	17K005	10/2019
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	17M005	12/2019
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	17M018	12/2019
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	18C001	03/2020
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	18C004	03/2020
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	18F019	06/2020
0904-5711-30	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), 1 oz	Major	18F032	06/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17E032	05/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17F011	06/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17F020	06/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17G003	07/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17G011	07/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17H016	08/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17J005	09/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17J017	09/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17J026	09/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17K029	10/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	17L027	11/2019
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18A003	01/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18A004	01/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18A033	01/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18B011	02/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18C029	03/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18D019	04/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18D025	04/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18F014	06/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18H029	08/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18J007	09/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18J018	09/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18K007	10/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	18K026	10/2020
0904-5711-35	Nasal Decongestant Spray (Oxymetazoline HCl 0.05%), ½ oz	Major	19A012	01/2021
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	17E016	05/2019
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	17E017	05/2019
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	17F023	06/2019
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	17F023A	06/2019
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	17L018	11/2019
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	17L029	11/2019
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	17L030	11/2019
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	17L031	11/2019

NDC No	Product Name	Label	Lot	Expiration
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	17M035	12/2019
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	18B002	02/2020
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	18B014	02/2020
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	18B035	02/2020
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	18C002	03/2020
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	18C019	03/2020
0904-6306-20	Robafen DM Cough Sugar-Free Clear (Dextromethrophan HBr, USP 10 mg/5 mL; Guaifenesin, USP 100 mg/5 mL), 4 oz	Major	18D013	04/2020
0904-6372-20	Cetirizine HCL Oral Solution, USP 1mg/mL, 4 oz	Major	17G012	07/2019
0904-6479-16	Robafen AC Oral Solution CV (Guaifenesin and Codeine Phosphate Oral Solution, USP) 100 mg/10 mg per 5 mL, 16 oz	Major	17M003	12/2019
0904-6479-16	Robafen AC Oral Solution CV (Guaifenesin and Codeine Phosphate Oral Solution, USP) 100 mg/10 mg per 5 mL, 16 oz	Major	18A009	01/2020
0904-6479-16	Robafen AC Oral Solution CV (Guaifenesin and Codeine Phosphate Oral Solution, USP) 100 mg/10 mg per 5 mL, 16 oz	Major	18A010	01/2020
0904-6479-16	Robafen AC Oral Solution CV (Guaifenesin and Codeine Phosphate Oral Solution, USP) 100 mg/10 mg per 5 mL, 16 oz	Major	18B024	02/2020
0904-6479-16	Robafen AC Oral Solution CV (Guaifenesin and Codeine Phosphate Oral Solution, USP) 100 mg/10 mg per 5 mL, 16 oz	Major	18F021	06/2020
0904-6479-16	Robafen AC Oral Solution CV (Guaifenesin and Codeine Phosphate Oral Solution, USP) 100 mg/10 mg per 5 mL, 16 oz	Major	18G009	07/2020
0904-6479-16	Robafen AC Oral Solution CV (Guaifenesin and Codeine Phosphate Oral Solution, USP) 100 mg/10 mg per 5 mL, 16 oz	Major	18G020	07/2020
0904-6479-16	Robafen AC Oral Solution CV (Guaifenesin and Codeine Phosphate Oral Solution, USP) 100 mg/10 mg per 5 mL, 16 oz	Major	18K005	10/2020
0904-6479-16	Robafen AC Oral Solution CV (Guaifenesin and Codeine Phosphate Oral Solution, USP) 100 mg/10 mg per 5 mL, 16 oz	Major	18K011	10/2020
0904-7688-22	Anu-Med brand of Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Major	17L008	05/2019
0904-7688-22	Anu-Med brand of Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Major	17M011	06/2019
0904-7688-22	Anu-Med brand of Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Major	17M037	06/2019
0904-7688-22	Anu-Med brand of Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Major	18A015	07/2019
0904-7688-22	Anu-Med brand of Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Major	18B012	08/2019
0904-7688-22	Anu-Med brand of Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Major	18B023	08/2019
0904-7688-22	Anu-Med brand of Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Major	18K023	04/2020
0904-7688-22	Anu-Med brand of Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Major	18K029	04/2020
0904-7688-22	Anu-Med brand of Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Major	18L014	05/2020
0904-7688-22	Anu-Med brand of Hemorrhoidal Suppositories (Phenylephrine HCl 0.25%; Hard Fat 88.7%), 12's	Major	19A001	07/2020

We request that you immediately take the following actions:

1. Immediately examine your inventory, quarantine product subject to the recall and stop distribution of the lot(s) identified above. If you have distributed any of the lots, please identify your retail customers and notify them at once of this product recall.
2. Please complete the Business Response Form requesting that you indicate one of the below:
  - You have examined your inventory and have none of the recalled product in stock or,
  - Upon examining your inventory, you have found the recalled product which will be quarantined. In the event you have recalled product, please return to Qualanex, LLC., using the Postage Paid Product Return label that will be provided and mail to the following:

Qualanex, LLC.  
1410 Harris Road  
Libertyville, IL 60048

3. If the product you are returning is DEA schedule IV or V controlled substances, please ensure you provide your DEA Registration number on the business response form.
4. Please return the Business Response Form once received via fax to 1-847-737-3719 or email to [Recall@qualanex.com](mailto:Recall@qualanex.com). Please return the Business Response Form regardless of whether you have recalled product in your possession or not.

This action applies only to the products addressed in this notification. Only product from these batch/lot will be accepted under the terms of this recall.

- If you have any medical questions regarding this recall or to report an adverse event, please contact Torrent Pharma Inc. at 1-800-912-9561 (8:00 am - 5:00 pm Eastern Time).
- If you have any general questions regarding the return of these products, please contact Qualanex at 1-888-504-2013 (8:00 am - 9:00 pm Eastern Time).

**To ensure proper credit, please return recalled merchandise before August 31, 2019.** Any other product sent in addition or in lieu of recalled product will be destroyed, without issuance of credit to your account.

We regret any inconvenience and appreciate your immediate cooperation.

Dale McPherson  
Manager, QRA  
Major and Rugby Laboratories

## URGENT DRUG RECALL BUSINESS RESPONSE FORM

Please fill out and either fax to (847) 737-3719 or email to [Recall@qualanex.com](mailto:Recall@qualanex.com).

As per Torrent Pharma, Inc's voluntary recall to the retail level for **all products and lots within expiry** manufactured at its Levittown, PA facility due to potential product contamination with *Burkholderia cepacia* (*B.cepacia*) and *Ralstonia pickettii* (*R. pickettii*), please indicate one of the below.

Please include your DEA Registration number on the business response form.

**Please check ALL appropriate boxes.**

- I have read and understand the recall instructions provided in the Recall Notification Letter – June 3,2019.
- I have identified and notified my customers that were shipped, or may have been shipped, this product (please **specify date and method of notification**);  
\_\_\_\_\_

- We have examined our inventories and have none of the recalled product in stock: (initials/Date) \_\_\_\_\_

or

- Upon reviewing our inventory, we have identified the following recalled product(s):

NDC: \_\_\_\_\_ Lot: \_\_\_\_\_

Quantity Being Returned    Full/Sealed Bottles/Carton    Partial Bottles/Carton

\_\_\_\_\_

NDC: \_\_\_\_\_ Lot: \_\_\_\_\_

Quantity Being Returned    Full/Sealed Bottles/Carton    Partial Bottles/Carton

\_\_\_\_\_

NDC: \_\_\_\_\_ Lot: \_\_\_\_\_

Quantity Being Returned    Full/Sealed Bottles/Carton    Partial Bottles/Carton

\_\_\_\_\_

NDC: \_\_\_\_\_ Lot: \_\_\_\_\_

Quantity Being Returned    Full/Sealed Bottles/Carton    Partial Bottles/Carton

\_\_\_\_\_

NDC: \_\_\_\_\_ Lot: \_\_\_\_\_

Quantity Being Returned    Full/Sealed Bottles/Carton    Partial Bottles/Carton

\_\_\_\_\_

NDC: \_\_\_\_\_ Lot: \_\_\_\_\_

Quantity Being Returned    Full/Sealed Bottles/Carton    Partial Bottles/Carton

\_\_\_\_\_

NDC: \_\_\_\_\_ Lot: \_\_\_\_\_

Quantity Being Returned    Full/Sealed Bottles/Carton    Partial Bottles/Carton

\_\_\_\_\_

**(If additional space is required, please provide information in an attachment to this response form.)**

Please check the appropriate box(es) to describe your business

- wholesaler/distributor     Retail Pharmacy     Other: \_\_\_\_\_
- hospital/medical facility     hospital pharmacies
- Retailer

Completed by:    (Please Print)

Name/Title: \_\_\_\_\_ Phone: \_\_\_\_\_

E-Mail: \_\_\_\_\_ Company Name: \_\_\_\_\_

Address: \_\_\_\_\_ City, State, Zip: \_\_\_\_\_

Wholesaler: \_\_\_\_\_ DEA Number: \_\_\_\_\_

Date: \_\_\_\_\_

Please Note: **All products and lots** manufactured at the Levittown, PA facility are subjected to this recall. These products and lots are indicated the attached Recall Notification Dated June 3, 2019. Please notify Qualanex if you identify any affected products.