

**URGENT DRUG RECALL**

Friday, October 26, 2018

Dear Valued Life-Assist Customer,

According to our records you have purchased a product that has been recalled by the manufacturer. Please examine your inventory to determine if you have the following product, with an affected lot number in your possession.

**METOPROLOL TARTRATE 5 mg, 5 ml VIAL**

Life-Assist, Inc. Product Code	NDC	Affected Lot Numbers
DR0033-10	36000-033-10	A061267, A061273, A061392, A061395, A061398, A061403, A061407, A0A0070, A0A0073, A0A0079, A0A0081, A0A0083, A0A0119, A0A0124, A0A0125, A0A0133, A0A0141, A0A0145, A0A0152, A0A0247, A0A0252, A0A0253, A0A0292, A0A0293, A0A0361, A0A0367, A0A0390, A0A0438, A0A0445, A0A0453, A0A0459, A0A0547, A0A0551, A0A0554, A0A0630, A0A0631, A0A0637, A0A0638, A0A0777, A0A0915, A0A0919, A0A0924, A0A0930, A0A1094, A0A1097, A0A1110

**Reason for Recall:**

Baxter Healthcare Corporation is issuing a voluntary drug recall for multiple lots of Metoprolol Tartrate Injection due to out-of-specification stability test results. Please read the enclosed recall notification from the manufacturer for more information.

**Action Required:**

1. Immediately forward this notification to any pertinent personnel, department, and/or location within your organization.
2. Check your inventory for the NDC with any of the specific lot numbers listed above.
3. Quarantine any product with an affected lot number. If the affected stock has been depleted, you may disregard this notification.
4. Contact Life-Assist Customer Service at 800-824-6016 or [saleservice@life-assist.com](mailto:saleservice@life-assist.com) to obtain a Return Authorization.

We apologize for any inconvenience.



# Urgent Drug Recall

October 15, 2018

Dear Director of Materials Management:

**Problem Description**

Baxter Healthcare Corporation is issuing a voluntary drug recall for multiple lots of Metoprolol Tartrate Injection due to out-of-specification stability test results. Specifically, Baxter has observed an upward shift in the pH of the solution within the shelf life of the impacted lots, resulting from the use of bromobutyl rubber closures in the packaging of the product. The affected lots were distributed between 2/1/2017 and 2/6/2018 in the United States.

**Affected Product**

Product Code	Product Description	Lot Number	Expiration Date	NDC
AIN00234	Metoprolol Tartrate Injection, USP 1 mg/mL	Refer to Attachment A	Refer to Attachment A	36000-033-10

**Hazard Involved**

This issue does not have the potential for adverse health consequences and there have been no associated adverse events reported.

**Actions to be taken by Customers**

1. Locate and remove all affected product lots from your facility. The NDC number and lot number can be found on the individual product or shipping carton.
2. Contact Qualanex on behalf of Baxter Healthcare to arrange for return and credit. Qualanex can be reached at 888-424-4341 between the hours of 7:00 am and 4:00 pm Central Time, Monday through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling.
3. **If you purchased this product directly from Baxter (formerly Claris Injectables Limited), complete the enclosed Baxter customer reply form and return it to Baxter by faxing it to 224-270-5457 or scanning and e-mailing it to [fca@baxter.com](mailto:fca@baxter.com), even if you do not have any inventory.** Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
4. If you purchased this product from a distributor, contact your supplier to arrange for return and credit. Please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.
5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please conduct a consumer-level recall of the affected product that you distributed to customers.

**Further information and support**

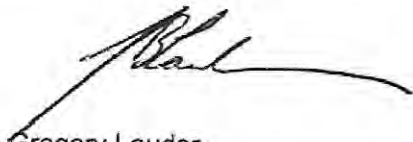
For general questions regarding this communication, contact Baxter Corporate Product Surveillance at 800-437-5176, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse reactions or quality problems experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Emailing to Baxter at: [corporate\\_product\\_complaints\\_round\\_lake@baxter.com](mailto:corporate_product_complaints_round_lake@baxter.com).
- Reporting to the FDA MedWatch Adverse Event Reporting Program:
  - **Online:** By completing and submitting the report online at: [www.fda.gov/medwatch/report](http://www.fda.gov/medwatch/report)
  - **Regular mail or Fax:** Download the form from [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form, or submit by fax to 800-332-0178.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,



Gregory Lauder  
Director, Quality  
Baxter Healthcare Corporation

cc: Director of Pharmacy

Enclosure: Baxter Customer Reply Form  
Attachment A: Affected Lot Numbers

## Attachment A: Affected Lot Numbers

Product Code	Product Description	Lot Number	Expiration Date	NDC
AIN00234	Metoprolol Tartrate injection, USP 1 mg/mL	A061267	10/2018	36000-033-10
		A061273	10/2018	
		A061392	11/2018	
		A061395	11/2018	
		A061398	11/2018	
		A061403	11/2018	
		A061407	11/2018	
		A0A0070	12/2018	
		A0A0073	12/2018	
		A0A0079	12/2018	
		A0A0081	12/2018	
		A0A0083	12/2018	
		A0A0119	1/2019	
		A0A0124	1/2019	
		A0A0125	1/2019	
		A0A0133	1/2019	
		A0A0141	1/2019	
		A0A0145	1/2019	
		A0A0152	1/2019	
		A0A0247	2/2019	
		A0A0252	2/2019	
		A0A0253	2/2019	
		A0A0292	2/2019	
		A0A0293	2/2019	
		A0A0361	3/2019	
		A0A0367	3/2019	
		A0A0390	3/2019	
		A0A0438	4/2019	
		A0A0445	4/2019	
		A0A0453	4/2019	
		A0A0459	4/2019	
		A0A0547	5/2019	
		A0A0551	5/2019	
A0A0554	5/2019			
A0A0630	5/2019			
A0A0631	5/2019			
A0A0637	5/2019			
A0A0638	5/2019			
A0A0777	7/2019			
A0A0915	8/2019			
A0A0919	8/2019			
A0A0924	8/2019			
A0A0930	8/2019			
A0A1094	11/2019			
A0A1097	11/2019			
A0A1110	11/2019			