



## UPDATED URGENT Drug Recall Notice

### Lidocaine Hydrochloride Jelly and Sodium Chloride Ophthalmic Ointment

**Date: 9/12/2022**

**Manufacturing Firm:**

**Company** Akorn Operating Company LLC  
**Address** 72 Veronica Ave.  
**City/State/Zip** Somerset, NJ 08873

**Recalling Firm (if applicable):**

**Company** Akorn Operating Company LLC  
**Address** 5605 Centerpoint Ct., Suite A  
**City/State/Zip** Gurnee, IL 60031

**PRODUCT:**

Product Name	Package Size	NDC	Lot	Expiration Date	Manufacturer Initial Ship Date
Lidocaine Hydrochloride Jelly USP, 2%	Pack of 10 x 5ml Tubes	17478-711-31 (Carton)	9J36A	8/31/2022	6/15/2020
			9J36B	8/31/2022	5/27/2020
			9J39A	8/31/2022	11/26/2019
			9J39B	8/31/2022	1/3/2020
			9J39C	8/31/2022	12/20/2019
			9J39D	8/31/2022	12/20/2019
		17478-711-10 (Tubes)	9J39E	8/31/2022	1/7/2020
			9J42B	8/31/2022	1/28/2020
			9J42C	8/31/2022	1/30/2020
			9K62A	9/30/2022	3/16/2020
			9K62B	9/30/2022	7/17/2020
			9K62C	9/30/2022	7/17/2020
			9M04A	11/30/2022	3/31/2020
			9M04B	11/30/2022	3/31/2020
Sodium Chloride Ophthalmic Ointment USP, 5%	3.5g Tube	17478-622-35	9J58A	8/31/2022	12/13/2019
			9J58B	8/31/2022	12/18/2019

**REASON:**

This voluntary recall is prompted by the identification of turbidity during sterility testing for a product manufactured on Fill Line #2. Akorn's expansion of the investigation has indicated that while additional products/lots were manufactured on the same line during the investigated timeframe, the assessment of sterility results for the batches listed above showed passing sterility results. Akorn's review of the environmental data associated with these batches showed no recoveries and no significant shifts or negative trends observed that would indicate systemic microbial contamination. Nonetheless, as a precautionary matter, Akorn is initiating a recall for all lots manufactured on Fill Line #2 during the investigated timeframe and within expiry.

**LEVEL:**

This recall is being carried out at the **RETAIL** level and is only for the specific lots listed above.

**CLASS:**

This recall has not yet been officially and publicly classified and is being conducted with the knowledge of the Food and Drug Administration.

**ACTION:**

By distributor:

1. Stop dispensing and distributing these lots. Quarantine product.
2. Please carry out a physical count and record this data on the verification form included with this letter.
3. Complete and return the attached verification form **even if you do not have the recalled product**.
4. Notifications of this recall are being sent to all direct distributor accounts of Akorn, please forward this notification to any sub-accounts.
5. Please complete the recall verification form and return to Qualanex via [recall@qualanex.com](mailto:recall@qualanex.com) or fax to 847-737-3719 so a Return Authorization form can be issued.
6. Once received, please include with the recalled product and return to the address below. Do not return your recalled product prior to receiving the RA.

**Akorn c/o  
Qualanex, LLC  
1410 Harris Road  
Libertyville, IL 60048**

**Other Information:** Provide necessary contact information for distributor/retailer, including contact for medical and product questions and cost recovery information.



No other lots, packages or formulations of this Product are being recalled at this time.

~~For shipping assistance, product questions or questions about the recall process, please contact Qualanex Customer Service at (800) 505-9291.~~

For medical questions or to report an Adverse Event, please contact Akorn at (800) 932-5676 or [customer.service@akorn.com](mailto:customer.service@akorn.com).

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- ☑ Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- ☑ Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience caused by this

**AUTHORIZED BY:**

Name: Jaime Santana

Title: Vice President, Global Quality Compliance

Signature: 

Date: 08/30/2022



McKesson Medical-Surgical Inc.  
Drug Recall Reply Form: RC-2022-159  
Akorn Lidocaine Hydrochloride Jelly

September 12, 2022

Complete this reply form and return all pages immediately via email to [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or fax at (866) 871-0270 should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

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

Your Name: \_\_\_\_\_ Email Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

Account: 464622 District: 0650000  
YALE UNIVERSITY  
ATTN: RISK MANAGEMENT  
PO BOX 208228  
NEW HAVEN, CT 06520-8228

I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for return.

Qty	Unit of Measure	MMS #	NDC #	Description
		1151247	17478-0711-31	LIDOCAINE HCL, JELLY 2% 5ML (10/CT)

\*Return Affected lot numbers only

**\* Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected lot numbers are listed on the McKesson customer letter.**

If you are on a McKesson truck route, a delivery professional will pick up the affected products, otherwise you will receive UPS return label(s) via email or fax.

I am on a McKesson truck route, please schedule a delivery professional pick up.

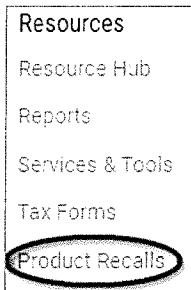
Please send my UPS/Return label by  Fax or  Email. Number of UPS Parcels to be returned: \_\_\_\_\_

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or call (800) 688-8840.

See instructions on the reverse side of this form to access McKesson Medical-Surgical's online product ordering system, "SupplyManager", for a fillable form.

**Instructions for the McKesson Medical-Surgical online product ordering system – “SupplyManager”, to access and download a “fillable” PDF reply form.**

- 1) It is important to download the correct reply form for the specific recall you are responding to.
  - a. Reply forms have a specific designation, example: RC-202X-XXX.
    - “202X” is the recall year, and “XXX” is the 3-digit unique numeric identifier for the recall.
- 2) Go to <https://mms.mckesson.com/> and log in to “SupplyManager”, with your username and password.
- 3) On the home page, under ‘Essential Tasks’ click ‘Your Account.’ Under ‘Resources’ a support link titled “Product Recalls” can be found on the right side.
- 4) Click on the hyperlink “Product Recalls” (this will open a listing of recalls for the last 3 months).



- 5) On the recalls list page, locate the “Find” box.
  - a. From the drop-down options, select one of the following: “Keyword”, “McKesson Item #” or “Manufacturer”.
  - b. Enter a Keyword, McKesson Item #, or Manufacturer name in the Find box and click “Find”.

Find  Manufacturer

- c. A list of issued recalls will be made visible for you to select from.
- 6) Click on the blue hyperlink, found under the heading “Recall Notice,” for the notice details you want to access.

Manufacturer	Recall Notice	Issued ▾
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- 7) The PDF customer documents associated with the notice will be displayed, *this includes the reply form to download and complete for your response.*
- 8) Click on the hyperlink(s) to open the Customer Document(s). Save/Download this document to your computer. Once the documents are saved, close out the document window.
- 9) Submit completed reply form to [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com).
- 10) If you wish to view additional recalls, return to the home recall page by clicking the blue “View All Recalls” button at the upper right corner of the page above the blue alert banner.





**URGENT DRUG RECALL**

September 12, 2022

Dear Valued McKesson Customer:

Akorn Operating Company LLC has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Drug Recall regarding specific lots of their Lidocaine Hydrochloride Jelly and Sodium Chloride Ophthalmic Ointment. This notice has been issued due to the identification of turbidity during sterility testing for a product manufactured on Fill Line #2. Affected product first shipped November 26, 2019.

This Urgent Drug Recall is being done with the knowledge of the U.S. Food and Drug Administration.

For clinical inquiries, please contact Akorn at **(800) 932-5676**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table for a list of affected item(s) distributed by McKesson Medical-Surgical

MMS #	NDC #	Description	Affected Lot(s)	Exp. Date	Affected Lot(s)	Exp. Date
1151247	17478-0711-31	LIDOCAINE HCL, JELLY 2% 5ML (10/CT)	9J36A	8/31/2022	9J42B	8/31/2022
			9J36B	8/31/2022	9J42C	8/31/2022
			9J39A	8/31/2022	9K62A	9/30/2022
			9J39B	8/31/2022	9K62B	9/30/2022
			9J39C	8/31/2022	9K62C	9/30/2022
			9J39D	8/31/2022	9M04A	11/30/2022
			9J39E	8/31/2022	9M04B	11/30/2022

**McKesson Customer Instructions:**

- 1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed in the item table. If you have no products matching the affected item(s) and lot number(s), no further action is needed.
- 2.) A copy of the Urgent Drug Recall from Akorn has been included for reference.
- 3.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.
  - **Please note:** Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected product lot numbers are listed in the item table. Once the product is returned, credit will be issued to you.
  - **Please place a new order for replacement product if there is an immediate need.**
- 4.) If you have further distributed any of the item(s) referenced in this notification, provide your Retail level accounts with a copy of this notification and request that they return the affected product directly to you.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

**McKesson Medical-Surgical Inc.**



McKesson Medical-Surgical Inc.  
 Drug Recall Reply Form: RC-2022-159A  
 Akorn Lidocaine Hydrochloride Jelly

September 21, 2022

Complete this reply form and return all pages immediately via email to [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or fax at (866) 871-0270 should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

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

Your Name: \_\_\_\_\_ Email Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

Account: 464622 District: 0650000  
 YALE UNIVERSITY  
 ATTN: RISK MANAGEMENT  
 PO BOX 208228  
 NEW HAVEN, CT 06520-8228

I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for return.

Qty	Unit of Measure	MMS #	NDC #	Description
		1088548	17478-0711-10	LIDOCAINE, JELLY 2% 5ML (10/CT)
		1151247	17478-0711-31	LIDOCAINE HCL, JELLY 2% 5ML (10/CT)

\*Return Affected lot numbers only

**\* Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected lot numbers are listed on the McKesson customer letter.**

If you are on a McKesson truck route, a delivery professional will pick up the affected products, otherwise you will receive UPS return label(s) via email or fax.

I am on a McKesson truck route, please schedule a delivery professional pick up.

Please send my UPS/Return label by  Fax or  Email. Number of UPS Parcels to be returned: \_\_\_\_\_

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or call (800) 688-8840.

See instructions on the reverse side of this form to access McKesson Medical-Surgical's online product ordering system, "SupplyManager", for a fillable form.

**Instructions for the McKesson Medical-Surgical online product ordering system – “SupplyManager”, to access and download a “fillable” PDF reply form.**

- 1) It is important to download the correct reply form for the specific recall you are responding to.
  - a. Reply forms have a specific designation, example: RC-202X-XXX.
    - “202X” is the recall year, and “XXX” is the 3-digit unique numeric identifier for the recall.
- 2) Go to <https://mms.mckesson.com/> and log in to “SupplyManager”, with your username and password.
- 3) On the home page, under ‘Essential Tasks’ click ‘Your Account.’ Under ‘Resources’ a support link titled “Product Recalls” can be found on the right side.
- 4) Click on the hyperlink “Product Recalls” (this will open a listing of recalls for the last 3 months).



- 5) On the recalls list page, locate the “Find” box.
  - a. From the drop-down options, select one of the following: “Keyword”, “McKesson Item #” or “Manufacturer”.
  - b. Enter a Keyword, McKesson Item #, or Manufacturer name in the Find box and click “Find”.

Find  Manufacturer ▼

- c. A list of issued recalls will be made visible for you to select from.
- 6) Click on the blue hyperlink, found under the heading “Recall Notice,” for the notice details you want to access.

Manufacturer	Recall Notice	Issued ▼
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- 7) The PDF customer documents associated with the notice will be displayed, *this includes the reply form to download and complete for your response.*
- 8) Click on the hyperlink(s) to open the Customer Document(s). Save/Download this document to your computer. Once the documents are saved, close out the document window.
- 9) Submit completed reply form to [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com).
- 10) If you wish to view additional recalls, return to the home recall page by clicking the blue “View All Recalls” button at the upper right corner of the page above the blue alert banner.





**URGENT DRUG RECALL**

September 21, 2022

Dear Valued McKesson Customer:

Akorn has notified McKesson Medical-Surgical Inc. (MMS) of an update to the Urgent Drug Recall issued on August 31, 2022, regarding specific lots of their Lidocaine Hydrochloride Jelly and Sodium Chloride Ophthalmic Ointment. This Urgent Drug Recall has been expanded to include an additional NDC number due to the identification of turbidity during sterility testing for a product manufactured on Fill Line # 2. Affected product first shipped September 26, 2019.

This Urgent Drug Recall is being done with the knowledge of the U.S. Food and Drug Administration.

For clinical inquiries, please contact Akorn at **(800) 932-5676**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table for a list of affected item(s) distributed by McKesson Medical-Surgical

MMS #	NDC #	Description	Affected Lot(s)	Exp. Date
1088548	17478-0711-10	LIDOCAINE, JELLY 2% 5ML (10/CT)	9J36A	8/31/2022
			9J36B	8/31/2022
			9J39A	8/31/2022
			9J39B	8/31/2022
			9J39C	8/31/2022
			9J39D	8/31/2022
			9J39E	8/31/2022
			9J42B	8/31/2022
			9J42C	8/31/2022
			9K62A	9/30/2022
			9K62B	9/30/2022
			9K62C	9/30/2022
			9M04A	11/30/2022
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1151247	17478-0711-31	LIDOCAINE HCL, JELLY 2% 5ML (10/CT)	9J36A	8/31/2022
			9J36B	8/31/2022
			9J39A	8/31/2022
			9J39B	8/31/2022
			9J39C	8/31/2022
			9J39D	8/31/2022
			9J39E	8/31/2022
			9J42B	8/31/2022
			9J42C	8/31/2022
			9K62A	9/30/2022
			9K62B	9/30/2022
			9K62C	9/30/2022
			9M04A	11/30/2022
			9M04B	11/30/2022

McKesson Medical-Surgical Inc.

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**McKesson Customer Instructions:**

- 1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed in the item table. If you have no products matching the affected item(s) and lot number(s), no further action is needed.
- 2.) A copy of the Urgent Drug Recall from Akorn has been included for reference.
- 3.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.
  - **Please note:** Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected product lot numbers are listed in the item table. Once the product is returned, credit will be issued to you.
  - **Please place a new order for replacement product if there is an immediate need.**
- 4.) If you have further distributed any of the item(s) referenced in this notification, provide your Retail level accounts with a copy of this notification and request that they return the affected product directly to you.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.



## URGENT Drug Recall Notice

### Lidocaine Hydrochloride Jelly and Sodium Chloride Ophthalmic Ointment

**Date: 8/31/2022**

**Manufacturing Firm:**

**Company** Akorn Operating Company LLC  
**Address** 72 Veronica Ave.  
**City/State/Zip** Somerset, NJ 08873

**Recalling Firm (if applicable):**

**Company** Akorn Operating Company LLC  
**Address** 5605 Centerpoint Ct., Suite A  
**City/State/Zip** Gurnee, IL 60031

**PRODUCT:**

Product Name	Package Size	NDC	Lot	Expiration Date	Manufacturer Initial Ship Date
Lidocaine Hydrochloride Jelly USP, 2%	30ml Tube	17478-711-31	9J36A	8/31/2022	6/15/2020
			9J36B	8/31/2022	5/27/2020
			9J39A	8/31/2022	11/26/2019
			9J39B	8/31/2022	1/3/2020
			9J39C	8/31/2022	12/20/2019
			9J39D	8/31/2022	12/20/2019
			9J39E	8/31/2022	1/7/2020
			9J42B	8/31/2022	1/28/2020
			9J42C	8/31/2022	1/30/2020
			9K62A	9/30/2022	3/16/2020
			9K62B	9/30/2022	7/17/2020
			9K62C	9/30/2022	7/17/2020
			9M04A	11/30/2022	3/31/2020
			9M04B	11/30/2022	3/31/2020
Sodium Chloride Ophthalmic Ointment USP, 5%	3.5g Tube	17478-622-35	9J58A	8/31/2022	12/13/2019
			9J58B	8/31/2022	12/18/2019

**REASON:**

This voluntary recall is prompted by the identification of turbidity during sterility testing for a product manufactured on Fill Line #2. Akorn's expansion of the investigation has indicated that while additional products/lots were manufactured on the same line during the investigated timeframe, the assessment of sterility results for the batches listed above showed passing sterility results. Akorn's review of the environmental data associated with these batches showed no recoveries and no significant shifts or negative trends observed that would indicate systemic microbial contamination. Nonetheless, as a precautionary matter, Akorn is initiating a recall for all lots manufactured on Fill Line #2 during the investigated timeframe and within expiry.

**LEVEL:**

This recall is being carried out at the **RETAIL** level and is only for the specific lots listed above.

**CLASS:**

This recall has not yet been officially and publicly classified and is being conducted with the knowledge of the Food and Drug Administration.

**ACTION:**

By distributor:

1. Stop dispensing and distributing these lots. Quarantine product.
2. Please carry out a physical count and record this data on the verification form included with this letter.
3. Complete and return the attached verification form **even if you do not have the recalled product**.
4. Notifications of this recall are being sent to all direct distributor accounts of Akorn, please forward this notification to any sub-accounts.
5. Please complete the recall verification form and return to Qualanex via [recall@qualanex.com](mailto:recall@qualanex.com) or fax to 847-737-3719 so a Return Authorization form can be issued.
6. Once received, please include with the recalled product and return to the address below. Do not return your recalled product prior to receiving the RA.

Akorn c/o  
Qualanex, LLC  
1410 Harris Road  
Libertyville, IL 60048

**Other Information:** Provide necessary contact information for distributor/retailer, including contact for medical and product questions and cost recovery information.





No other lots, packages or formulations of this Product are being recalled at this time.

~~For shipping assistance, product questions or questions about the recall process, please contact Qualanex Customer Service at (800) 505-9291.~~

For medical questions or to report an Adverse Event, please contact Akorn at (800) 932-5676 or [customer.service@akorn.com](mailto:customer.service@akorn.com).

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience caused by this

**AUTHORIZED BY:**

Name: Jaime Santana

Title: Vice President, Global Quality Compliance

Signature: 

Date: 09/09/2022



McKesson Medical-Surgical  
Drug Recall Reply Form: RC-2022-083A  
Sun Pharma Medroxyprogesterone Acetate Injectable

May 23, 2022

Complete this reply form and return all pages immediately via email to [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or fax at (866) 871-0270 should you have affected product.

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

Your Name: \_\_\_\_\_ Email Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

Account: 464622 District: 0650000  
YALE UNIVERSITY  
ATTN: RISK MANAGEMENT  
PO BOX 208228  
NEW HAVEN, CT 06520-8228

I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for return.

Qty	Unit of Measure	MMS #	NDC #	Description
		1191457	16714-0981-01	MEDROXYPROGESTERONE, SDV 150MG/ML 1ML

\*Return Affected lot numbers only

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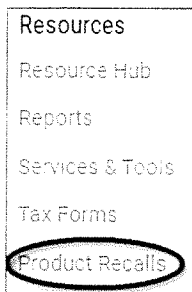
I am on a McKesson truck route, please schedule a delivery professional pick up.  
 Please send my UPS/Return label by  Fax or  Email. Number of UPS Parcels to be returned: \_\_\_\_\_

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or call (800) 688-8840.

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Find  Manufacturer

- c. A list of issued recalls will be made visible for you to select from.
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Manufacturer	Recall Notice	Issued ~
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- 7) The PDF customer documents associated with the notice will be displayed, *this includes the reply form to download and complete for your response.*
- 8) Click on the hyperlink(s) to open the Customer Document(s). Save/Download this document to your computer. Once the documents are saved, close out the document window.
- 9) Submit completed reply form to [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com).
- 10) If you wish to view additional recalls, return to the home recall page by clicking the blue “View All Recalls” button at the upper right corner of the page above the blue alert banner.



**URGENT: DRUG RECALL (REVISED TO RETAIL LEVEL)**

**Medroxyprogesterone Acetate Injectable Suspension, 150 mg/ml**

May 17, 2022

Dear Customer,

This notice is to inform you of a voluntary product recall involving the following twenty-seven (27) lots of Medroxyprogesterone Acetate Injectable Suspension, USP, 150 mg/ml:

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Medroxyprogesterone Acetate Injectable Suspension USP, 150 mg/ml	1 ml Pre-Filled Syringe	JKX4312A	50102-591-40	09/2022
		JKX4313A	50102-591-40	09/2022
		JKX4827A	50102-591-40	09/2023
		HAC1290A	50102-591-40	06/2023
		HAC2082B	50102-591-40	06/2023
		HAC1289A	16714-999-01	06/2023
		JKX2679A	16714-999-01	06/2022
		JKX3762A	16714-999-01	08/2022
		HAC0164A	16714-999-01	06/2023
		HAC1951A	62756-091-40	06/2023
	1 ml Vial	HAC2075A	16714-981-01	06/2023
		HAC2076A	16714-981-01	07/2023
		HAC2077A	16714-981-01	08/2023
		HAC2078A	16714-981-01	08/2023
		HAC3803A	16714-981-01	09/2023
		HAC0551A	16714-981-01	02/2023
		HAC0562A	16714-981-01	03/2023
		HAC1183A	16714-981-01	03/2023
		HAC1807A	16714-981-01	06/2023
		JKX6017A	16714-981-01	12/2022
		JKX6018A	16714-981-01	12/2022
		HAC0163A	16714-981-01	01/2023
		HAC1184A	16714-981-01	04/2023
		HAC0162A	16714-981-01	12/2022
		HAC2074A	62756-090-40	06/2023
		HAC0163B	62756-090-40	01/2023
		HAC1741A	62756-090-40	04/2023

For return of affected product, please email [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) or call 1-855-884-7515.





Sun Pharma is sending this letter as a revision to an earlier wholesale level recall letter dated May 6, 2022 in regards to the same twenty-seven (27) lot numbers of Medroxyprogesterone Acetate Injectable Suspension USP, 150 mg/ml in the table above. This recall is revised from the depth of wholesale level to retail level.

See enclosed product labeling.

This product recall has been initiated due to a lack of assurance of sterility for Medroxyprogesterone Acetate Injectable Suspension USP, 150 mg/ml 1 ml Pre-Filled Syringe and 1 ml Vial. An investigation was conducted and found that no sterility failure has been observed for any batches distributed for the market. However, out of an abundance of caution, Sun Pharma has voluntarily decided to recall all currently distributed batches of Medroxyprogesterone Acetate Injectable Suspension USP, 150 mg/ml 1 ml Pre-Filled Syringe and 1 ml Vial.

Based on the Health Hazard Evaluation conducted by Sun Pharma, use of this product is unlikely to pose any risk to patient safety.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on September 20<sup>th</sup>, 2020.

Immediately examine your inventory and quarantine the lot numbers subject to recall. In addition, if you have further distributed this product, please identify your retail customers and notify them at once of this product recall. Your notification to your retail customers may be enhanced by including a copy of this recall notification letter.

~~Please complete and return the enclosed response form as soon as possible. After receipt of the response form, a return kit will be provided so the affected product can be sent to:~~

~~Inmar, Inc.  
3845 Grand Lakes Way  
Suite 125  
Grand Prairie, TX 75050~~

If you have any questions, contact Inmar, Inc. at [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) or call 1-855-884-7515 Monday to Friday from 8:30 am to 5:00 pm (EST).

This recall should be carried out to the retail level.

Your assistance is appreciated and necessary to prevent patient harm.

This recall is being made with the knowledge of the Food and Drug Administration.

 May 17, 2022

James Mullen  
Sun Pharmaceutical Industries, Inc.  
Manager, Cluster Quality Support

~~For return of affected product, please email [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) or call 1-855-884-7515.~~



**URGENT DRUG RECALL**

May 23, 2022

Dear Valued McKesson Customer:

Sun Pharma has notified McKesson Medical-Surgical (MMS) of an Urgent Drug Recall regarding specific lots of their Medroxyprogesterone Acetate Injectable Suspension USP, 150 mg/ml. This notice has been issued due to a lack of assurance of sterility. Affected product first shipped September 20, 2020.

This Urgent Drug Recall is being done with the knowledge of the U.S. Food and Drug Administration.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table for a list of affected item(s) distributed by McKesson Medical-Surgical

MMS #	NDC #	Description	Affected Lot(s)	Exp. Date	Affected Lot(s)	Exp. Date
1191457	16714-0981-01	MEDROXYPROGESTERONE, SDV 150MG/ML 1ML	HAC2075A	06/2023	HAC1183A	03/2023
			HAC2076A	07/2023	HAC1807A	06/2023
			HAC2077A	08/2023	JKX6017A	12/2022
			HAC2078A	08/2023	JKX6018A	12/2022
			HAC3803A	09/2023	HAC0163A	01/2023
			HAC0551A	02/2023	HAC1184A	04/2023
			HAC0562A	03/2023	HAC0162A	12/2022

**McKesson Customer Instructions:**

- 1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed in the item table. If you have no products matching the affected item(s) and lot number(s), no further action is needed.
- 2.) A copy of the Urgent Drug Recall from Sun Pharma has been included for reference.
- 3.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.
  - **Please note:** Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected product lot numbers are listed in the item table. Once the product is returned, credit will be issued to you.
  - **Please place a new order for replacement product if there is an immediate need.**
- 4.) If you have further distributed any of the item(s) referenced in this notification, provide your Retail level accounts with a copy of this notification and request that they return the affected product directly to you.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at [MMSRecalls@McKesson.com](mailto:MMSRecalls@McKesson.com) or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical, Inc.

**McKesson Medical-Surgical, Inc.**



# MEDLINE INDUSTRIES, LP IMMEDIATE ACTION REQUIRED RECALL

07/20/2022

**1223930  
YALE UNIVERSITY  
PO BOX 208228  
NEW HAVEN, CT 06520-8228**

Dear Valued Medline Customer:

This letter is to inform you that Medline Industries, LP issued a recall for specific item(s) and lot(s) of Micro-Kill Beach - Individually Wrapped. Medline Industries, LP. is recalling our individually wrapped Micro-Kill Bleach Wipes because they did not meet the specification claim on the labeled active ingredient sodium hypochlorite.

**REQUIRED ACTION:**

1. Immediately check your stock for the affected item number and the affected lot numbers listed on the recall portal. Destroy affected product.
2. Please use the link and the information below to complete your response form. Please list the quantity of affected product you have in inventory on the form. Even if you do not have any affected product in inventory, please complete and submit the form.

The login for completing the response form is:

Website link: <https://recalls.medline.com>

Recall Reference #: R-22-073

Recall Code: R7E5CA2C

3. Upon completion of the form, please destroy affected product. Your account will receive credit once the response form is submitted.
4. If you are a distributor, or have resold or transferred this product to another company or individual, you are required by FDA regulations to notify them of this recall communication. Have the customers document and destroy any affected product. You should include your customers quantities on your response form.

If you have any questions, please contact the Recall Department at 866-359-1704.

We apologize for any inconvenience this may have caused. We, like you, place the health and safety of your patients first and foremost.

Sincerely,  
Kassandra Cotner (kcotner)  
RA Associate/Recalls

**Medline Industries, LP.**

Three Lakes Drive  
Northfield, IL 60093-2753

Toll Free: 866.359.1704  
Website: [medline.com](http://medline.com)

Email: [Recalls@Medline.com](mailto:Recalls@Medline.com)  
Fax: 866.767.1290