



URGENT VOLUNTARY RECALL: Distributor Level, Initiated February 7, 2023.

Voluntary recall of Drug Products manufactured at FEI # 3004011473, Intas Pharmaceuticals Ltd.

In an abundance of caution, Accord Healthcare, Inc. ("Accord"), is voluntarily recalling certain drug products identified in Attachment I (the "Drug Products") within expiry manufactured in one of the facilities that manufactures products for distribution by Accord US. The manufacturing site identified as FEI# 3004011473 was subject to an inspection by the United States Food and Drug Administration that concluded on December 2, 2022. At the conclusion of the inspection, the inspectors issued several Observations on Form 483. Accord takes this very seriously and is taking all appropriate measures to address them including, in an abundance of caution, recalling all products manufactured at that facility that are within expiry and do not fall into an exempted list of products determined by FDA. The exempted products will be subject to further testing and review. This recall is not due to any particular product complaint or determination of out of specification results.

Please examine your inventory of Accord's Drug Products for the Lot numbers identified in Attachment I.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the Lot numbers that are listed in Attachment I.
- Immediately discontinue distribution of all the Lot numbers that are listed in Attachment I.
- Promptly complete the attached recall stock response form.

Completed Recall Stock Response form should be mailed, emailed, or sent via FAX to INMAR, Attn: Recall Coordinator, One West Fourth Street, Suite 500 Winston Salem, NC 27101. INMAR Email: rxrecalls@inmar.com. FAX: 817-868-5362.

INMAR will send you a Return Goods Authorization and shipping label. Appropriate credit for returned product plus handling and shipping expenses will be issued to you upon receipt of the recalled product with the completed Return Goods Authorization. All recalled products returned without a Return Goods Authorization may delay the issuance of your credit.

Accord is working with Inmar Inc. to complete this recall. This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is much appreciated.

Sincerely,

Sabita Nair
Accord Healthcare Inc.



RECALL RESPONSE FORM

Product Recall Date: February 7, 2023

Voluntary recall of Drug Products manufactured at FEI # 3004011473- Intas Pharmaceuticals Ltd.

(Lot numbers listed in Attachment I)

Voluntary Recall: Distributor Level

Please fill out this form completely. By doing so, you acknowledge and agree that you have read and understand the recall instructions and have taken the appropriate action.

Distributor Name _____ DEA # _____ *
**DEA # is required, if not provided the processing of your form will be delayed.*
Address _____
City _____ State _____
Zip _____
Contact Name (please print) _____ Telephone # _____
Contact Signature _____ Date _____

Item description	NDC	Lot	Quantity Returning
See Attachment -I	See Attachment -I	See Attachment -I	

If you did not purchase the product directly from the Manufacturer, please complete the following section:

Purchased from: Name _____
DEA # _____
Address _____
City _____ State _____
Zip _____

I have checked my stock and:

_____ Do not have any stock of the recalled product.

AND

_____ Have quarantined and listed in the box above the quantity of units of the Lot numbers that are listed in Attachment I and will be returning them to Inmar, as soon as possible.

Upon receipt of this Response Form, Inmar will issue a shipping label(s).

Please indicate the number of labels needed: _____

Please fax this form to: 1-817-868-5362 or E-mail at: rxrecalls@inmar.com. Questions - 1-877-566-6108.

NDC	Product Name	Lot #	Units to return	NDC	Product Name	Lot #	Units to return
16729-280-01	ARIPIPRAZOLE T	P2102144		16729-003-16	GLIMEPIRIDE	R2100739	
16729-280-01	ARIPIPRAZOLE T	P2106903		16729-003-16	GLIMEPIRIDE	R2100738	
16729-280-01	ARIPIPRAZOLE T	P2204437		16729-003-16	GLIMEPIRIDE	R2100740	
16729-280-01	ARIPIPRAZOLE T	P2206101		16729-003-16	GLIMEPIRIDE	P2104668	
16729-280-10	ARIPIPRAZOLE T	P2006421		16729-003-16	GLIMEPIRIDE	P2104669	
16729-280-10	ARIPIPRAZOLE T	P2004882		16729-003-16	GLIMEPIRIDE	P2104670	
16729-280-10	ARIPIPRAZOLE T	P2004939		16729-003-16	GLIMEPIRIDE	P2105283	
16729-280-10	ARIPIPRAZOLE T	P2004883		16729-003-16	GLIMEPIRIDE	P2105291	
16729-280-10	ARIPIPRAZOLE T	P2004940		16729-003-16	GLIMEPIRIDE	P2105282	
16729-280-10	ARIPIPRAZOLE T	P2004942		16729-003-16	GLIMEPIRIDE	P2105794	
16729-280-10	ARIPIPRAZOLE T	P2004943		16729-003-16	GLIMEPIRIDE	P2105292	
16729-280-10	ARIPIPRAZOLE T	P2004944		16729-003-16	GLIMEPIRIDE	P2105297	
16729-280-10	ARIPIPRAZOLE T	P2107593		16729-003-16	GLIMEPIRIDE	P2105293	
16729-280-10	ARIPIPRAZOLE T	P2106907		16729-003-16	GLIMEPIRIDE	P2105295	
16729-280-10	ARIPIPRAZOLE T	P2106906		16729-003-16	GLIMEPIRIDE	P2105294	
16729-280-10	ARIPIPRAZOLE T	P2106908		16729-003-16	GLIMEPIRIDE	R2101408	
16729-280-10	ARIPIPRAZOLE T	P2106909		16729-003-16	GLIMEPIRIDE	R2101409	
16729-280-10	ARIPIPRAZOLE T	P2204654		16729-003-16	GLIMEPIRIDE	R2101410	
16729-280-10	ARIPIPRAZOLE T	P2204597		16729-003-16	GLIMEPIRIDE	R2101411	
16729-280-10	ARIPIPRAZOLE T	P2205348		16729-003-16	GLIMEPIRIDE	R2101412	
16729-281-10	ARIPIPRAZOLE T	P2004997		16729-003-16	GLIMEPIRIDE	R2101413	
16729-281-10	ARIPIPRAZOLE T	P2004998		16729-003-16	GLIMEPIRIDE	R2200089	
16729-281-10	ARIPIPRAZOLE T	P2004999		16729-003-16	GLIMEPIRIDE	R2200097	
16729-281-10	ARIPIPRAZOLE T	P2101206		16729-003-16	GLIMEPIRIDE	R2200100	
16729-281-10	ARIPIPRAZOLE T	P2102486		16729-003-16	GLIMEPIRIDE	R2200101	
16729-281-10	ARIPIPRAZOLE T	P2106247		16729-003-16	GLIMEPIRIDE	R2200088	
16729-281-10	ARIPIPRAZOLE T	P2105375		16729-003-16	GLIMEPIRIDE	P2200775	
16729-281-10	ARIPIPRAZOLE T	P2107239		16729-003-16	GLIMEPIRIDE	P2200776	
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16729-281-10	ARIPIPRAZOLE T	P2204222		16729-003-16	GLIMEPIRIDE	P2201348	
16729-278-01	ARIPIPRAZOLE T	P2102940		16729-003-16	GLIMEPIRIDE	R2200481	
16729-278-01	ARIPIPRAZOLE T	P2105793		16729-003-16	GLIMEPIRIDE	R2200576	
16729-278-01	ARIPIPRAZOLE T	P2205363		16729-003-16	GLIMEPIRIDE	P2203378	
16729-282-01	ARIPIPRAZOLE T	P2104086		16729-003-16	GLIMEPIRIDE	P2203379	
16729-282-01	ARIPIPRAZOLE T	P2205370		16729-003-16	GLIMEPIRIDE	P2203377	
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16729-283-10	ARIPIPRAZOLE T	P2100002		16729-003-16	GLIMEPIRIDE	R2200964	
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16729-434-05	DAPTOMYCIN	R2201261	
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