



**CardinalHealth**

URGENT PRODUCT RECALL

10/07/2020

RE: CARDINAL HEALTH NOTICE #103700

Dear Valued Customer:

According to our records you have purchased an item that has been recalled or withdrawn by the vendor. Please examine your stock to determine if you have the following product(s) with the affected lot number(s) in your possession. See below for the product disposition instructions established by the vendor. If you have any questions, please contact Cardinal Health Customer Service.

Vendor: TIME-CAP LABS

Event: Recall

Class: Unclassified

Level: Consumer

Return Product To: Cardinal Health

Reason: This Recall is being initiated because it was observed that various lots exceed the acceptable level of N-Nitrosodimethylamine (NDMA) content. This is a Consumer Level Recall. Pharmacies must notify their customers. The first distribution date was 1/15/2019. Consumers should continue taking the impacted product until a doctor or pharmacist gives them a replacement of a different treatment option.

**\*RETAIL CHAINS: PLEASE FOLLOW YOUR STANDARD CORPORATE POLICY FOR RECALLED AND WITHDRAWN ITEMS\***

Legal Disclaimer: Cardinal Health notifications regarding product recalls and withdrawals are designed to provide information about such products that have been recalled or withdrawn from the U.S. market by manufacturers, importers, private label distributors among others (collectively referred to as "Vendors"). The information that you will receive is based solely upon information provided to Cardinal Health by the Vendors of these products, or their assigned agents, and Cardinal Health makes no representations and disclaims all express and implied warranties and conditions of any kind, including, representations, warranties or conditions regarding accuracy, timeliness and completeness. Any specific inquiries regarding the details of a particular product and the reasons for a recall or withdrawal should be directed to the Vendor of that product.

**By acknowledging this recall or withdrawal on behalf of my organization, I explicitly agree to and state the following**

- I have the authority to respond to or receive product recalls and withdrawal notices on behalf of my organization.
- I have read and understand the instructions for properly handling this recall or withdrawal.
- Our organization agrees to promptly examine all product associated with this recall or withdrawal and check for any affected product.

- Our organization agrees to follow the instructions for handling of the product affected by this product recall or withdrawal.
- Our organization will follow existing Cardinal Health return goods policies and practices, including the following:
  1. Return Authorization (using return code 60) must accompany product being returned in order to receive credit.
  2. Partial of recalled/withdrawn Controlled Substances must be returned directly to the Vendor to receive credit.
  3. Partial of less than 25 percent of the original package quantity will not receive credit from Cardinal Health.
- Our organization agrees to electronically acknowledge the receipt of a recall or withdrawal notification, if this notification is received electronically via this system from Cardinal Health.
- Our organization agrees that if a hard copy notification is received from Cardinal Health, a signed hard copy acknowledgment is required to be returned to Cardinal Health.

Customer Signature / Date:

Items Affected:

NDC: 49483062301

CARDINAL HEALTH

<b>ITEM NUMBER</b>	<b>PRODUCT DESCRIPTION</b>
5370663	METFORMIN ER TB 500MG 100 CPLT

Lot Number(s):

- XP0010
- XP0016
- XP0046
- XP8260

NDC: 49483062401

CARDINAL HEALTH

<b>ITEM NUMBER</b>	<b>PRODUCT DESCRIPTION</b>
5374756	METFORMIN ER TB 750MG100 CPLT OPM
5353958	METFORMIN ER TB 750MG 100 CPLT

Lot Number(s):

- 9R0001
- 9R0002
- 9R0003
- 9R0004
- 9R0005
- 9R0006
- 9R0007
  
- 9R9001

- 9R9002
- C084F
- D001F
- E063F
- F072F
- F073F
  
- J002F
- J087F
- K080F
- L056F
- M046F
- M125E
- XR0016

NDC: 49483062310  
 CARDINAL HEALTH

<b>ITEM NUMBER</b>	<b>PRODUCT DESCRIPTION</b>
5374731	METFORMIN ER TB 500MG1000CPLT OPM
5370671	METFORMIN ER TB 500MG 1000 CPLT

Lot Number(s):

- A009G
- A40002
- A40004
- A40012
- A40014
- A40017
- D086F
  
- G012F
- K042F
- L008F
- M001F

NDC: 49483062350  
 CARDINAL HEALTH

<b>ITEM NUMBER</b>	<b>PRODUCT DESCRIPTION</b>
5325683	METFORMIN ER TB 500MG 500 CPLT

Lot Number(s):

- A010G
- A115G
- A40006
- A40007

- A40008
- A40011
- A40016

- A40018
- E037F
- E072F
- E074F
- F001F
- G011F
- H041F

- K051F
- L009F

NDC: 49483062309

CARDINAL HEALTH

**ITEM NUMBER**

**PRODUCT DESCRIPTION**

5370655

METFORMIN ER TB 500MG 90 CPLT

5374723

METFORMIN ER TB 500MG 90 CPLT OPM

Lot Number(s):

- A002G
- A003G
- A007G
- A40001
- A40003
- A40005
- A40009

- A40010
- A40013
- A40015
- A49001
- D096F
- E076F
- H029F

- H031F
- H039F
- J022F
- J092F
- K079F
- L007F
- L055F

- XP0036
- XP8276
- XP8289