



# Clifton Health Department Food Recall Notification



## Food/Drug/Pet Recall: Marksans Pharma Limited

Marksans Pharma Limited, India is voluntarily expanding its earlier initiated recall on June 05, 2020 to include an additional 76 unexpired lots of Metformin Hydrochloride Extended-Release Tablets, USP 500mg, & 750mg to the consumer level. Marksans performed N-Nitrosodimethylamine (NDMA) testing of unexpired identified marketed lots and observed that NDMA content in some lots is exceeding the acceptable Daily Intake Limit (ADI) of 96ng/day, therefore, out of an abundance of caution, an additional 76 lots are being recalled.

Risk Statement: NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant found in water and foods, including meats, dairy products and vegetables. Marksans Pharma Limited has not received any reports of adverse events that have been related to this recall.

Metformin Hydrochloride Extended-Release Tablets, USP 500mg & 750mg are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus and is packaged in HDPE bottles with the following NDC#s in different packing configurations-

Metformin Hydrochloride Extended-Release Tablets, USP 500mg:

90 counts: 49483-623-09

100 counts: 49483-623-01

500 counts: 49483-623-50

1000 counts: 49483-623-10

Metformin Hydrochloride Extended-Release Tablets, USP 750mg:

100 counts: 49483-624-01

The affected Metformin Hydrochloride Extended-Release Tablets, USP 500mg, are white to off white, capsule shaped, biconvex tablets, debossed with '101' on one side and plain on the other side and Metformin Hydrochloride Extended-Release Tablets, USP 750mg, are white to off white, capsule shaped, biconvex tablets, debossed with '102' on one side and plain on the other side.

S.No. Product Name NDC No. Pack Size Lot # Expiry Date

1. Metformin HCL ER Tablets



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- USP 500 mg 49483-623-50 500 E037F Oct-20
- 2. Metformin HCL ER Tablets
- USP 500 mg 49483-623-50 90 E072F Oct-20
- 3. Metformin HCL ER Tablets
- USP 500 mg 49483-623-50 90 E074F Oct-20
- 4. Metformin HCL ER Tablets
- USP 500 mg 49483-623-10 1000 D086F Oct-20
- 5. Metformin HCL ER Tablets
- USP 500 mg 49483-623-50 500 G011F Oct-20
- 6. Metformin HCL ER Tablets
- USP 500 mg 49483-623-09 90 E076F Oct-20
- 7. Metformin HCL ER Tablets
- USP 500 mg 49483-623-01 100 XP8260 Oct-20
- 8. Metformin HCL ER Tablets
- USP 500 mg 49483-623-10 1000 G012F Nov-20
- 9. Metformin HCL ER Tablets
- USP 500 mg 49483-623-09 90 D096F Nov-20
- 10. Metformin HCL ER Tablets
- USP 500 mg 49483-623-09 90 XP8276 Nov-20
- 11. Metformin HCL ER Tablets
- USP 500 mg 49483-623-50 500 F001F Nov-20
- 12. Metformin HCL ER Tablets
- USP 500 mg 49483-623-09 90 H029F Nov-20
- 13. Metformin HCL ER Tablets
- USP 500 mg 49483-623-09 90 H031F Nov-20
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- 14. Metformin HCL ER Tablets
- USP 500 mg 49483-623-09 90 XP8289 Nov-20
- 15. Metformin HCL ER Tablets
- USP 500 mg 49483-623-50 500 H041F Dec-20
- 16 Metformin HCL ER Tablets
- USP 500 mg 49483-623-09 90 L007F Dec-20
- 17. Metformin HCL ER Tablets
- USP 500 mg 49483-623-10 1000 L008F Dec-20
- 18. Metformin HCL ER Tablets
- USP 500 mg 49483-623-50 500 L009F Dec-20
- 19. Metformin HCL ER Tablets
- USP 500 mg 49483-623-09 90 J022F Dec-20
- 20. Metformin HCL ER Tablets



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USP 500 mg 49483-623-09 90 H039F Dec-20  
21. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 J092F Jan-21  
22. Metformin HCL ER Tablets  
USP 500 mg 49483-623-10 1000 K042F Feb-21  
23. Metformin HCL ER Tablets  
USP 500 mg 49483-623-50 500 K051F Jun-21  
24 Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 L055F Jun-21  
25. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 K079F Jul-21  
26. Metformin HCL ER Tablets  
USP 500 mg 49483-623-10 1000 M001F Jul-21  
27 Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A002G Aug-21  
28. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A003G Aug-21

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29. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A007G Aug-21  
30. Metformin HCL ER Tablets  
USP 500 mg 49483-623-50 500 A115G Sep-21  
31. Metformin HCL ER Tablets  
USP 500 mg 49483-623-50 500 A010G Sep-21  
32. Metformin HCL ER Tablets  
USP 500 mg 49483-623-10 1000 A009G Sep-21  
33. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A49001 Nov-21  
34. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A40001 Dec-21  
35. Metformin HCL ER Tablets  
USP 500 mg 49483-623-10 1000 A40002 Dec-21  
36. Metformin HCL ER Tablets  
USP 500 mg 49483-623-01 100 XP0010 Dec-21  
37. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A40003 Dec-21  
38. Metformin HCL ER Tablets  
USP 500 mg 49483-623-10 1000 A40004 Dec-21



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39. Metformin HCL ER Tablets  
USP 500 mg 49483-623-01 100 XP0016 Dec-21
40. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A40005 Dec-21
41. Metformin HCL ER Tablets  
USP 500 mg 49483-623-50 500 A40006 Jan-22
42. Metformin HCL ER Tablets  
USP 500 mg 49483-623-50 500 A40007 Jan-22
43. Metformin HCL ER Tablets  
USP 500 mg 49483-623-50 500 A40008 Jan-22
- S.No. Product Name NDC No. Pack Size Lot # Expiry Date
44. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A40009 Feb-22
45. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A40010 Mar-22
46. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 XP0036 Mar-22
47. Metformin HCL ER Tablets  
USP 500 mg 49483-623-50 500 A40011 Mar-22
48. Metformin HCL ER Tablets  
USP 500 mg 49483-623-10 1000 A40012 Mar-22
49. Metformin HCL ER Tablets  
USP 500 mg 49483-623-01 100 XP0046 Apr-22
50. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A40013 Mar-22
51. Metformin HCL ER Tablets  
USP 500 mg 49483-623-10 1000 A40014 Apr-22
52. Metformin HCL ER Tablets  
USP 500 mg 49483-623-09 90 A40015 Apr-22
53. Metformin HCL ER Tablets  
USP 500 mg 49483-623-50 500 A40016 Apr-22
54. Metformin HCL ER Tablets  
USP 500 mg 49483-623-10 1000 A40017 Apr-22
55. Metformin HCL ER Tablets  
USP 500 mg 49483-623-50 500 A40018 Apr-22
56. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 M125E Oct-20
57. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 D001F Nov-20



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58. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 C084F Nov-20

S.No. Product Name NDC No. Pack Size Lot # Expiry Date

59. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 F073F Jan-21

60. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 E063F Jan-21

61. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 F072F Mar-21

62. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 J002F Apr-21

63. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 J087F Apr-21

64. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 K080F Jun-21

65. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 L056F Jun-21

66. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 M046F Jul-21

67. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 9R9001 Oct-21

68. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 9R9002 Nov-21

69. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 9R0001 Dec-21

70. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 9R0002 Dec-21

71. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 9R0003 Mar-22

72. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 XR0016 Mar-22

73. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 9R0004 Mar-22

S.No. Product Name NDC No. Pack Size Lot # Expiry Date

74. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 9R0005 Mar-22

75. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 9R0006 Apr-22



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76. Metformin HCL ER Tablets  
USP 750 mg 49483-624-01 100 9R0007 Apr-22

Metformin Hydrochloride Extended-Release Tablets, USP 500mg & 750 mg were distributed by Time-Cap Labs, Inc. (located at 7 Michael Avenue, Farmingdale, New York 11735) nationwide in the USA to wholesalers who further distributed to pharmacies.

Marksans Pharma Limited is notifying its distributors and customers by issuing notification letter and press release and is arranging for return/replacement etc. of recalled product lots. Distributors //customers that have affected lots of Metformin Hydrochloride Extended- Release Tablets, USP 500mg & 750mg those are being recalled should return to place of purchase. The lot # can be located on the side panel of bottle labels as well as shipper/case labels.

Consumers with questions regarding this recall and return can contact Ms. Irene McGregor (Vice President, Regulatory Affairs) of Time-Cap Labs, Inc., located at 7 Michael Avenue, Farmingdale, New York 11735, by phone number 631-753-9090: ext. 160, [Monday to Friday 8am-5pm EST] or e-mail address [imcgregor@timecaplabs.com](mailto:imcgregor@timecaplabs.com).

Consumers taking these recalled product lots of Metformin ER Tablets should continue taking it until a doctor or pharmacist gives them a replacement or a different treatment option. It could be dangerous for patients with type 2 diabetes to stop taking their metformin without first talking to their health care professional. Consumer should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

Complete and submit the report Online

Regular Mail or Fax: Download form 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.