

URGENT: DRUG RECALL

TACROLIMUS OINTMENT, 0.1%,

30 G (NDC 68462-534-35), 60 G (NDC 68462-534-65) & 100 G (NDC 68462-534-94),

July 11, 2022

Dear Customer,

This is to inform you of a voluntary recall at Wholesaler level involving the following:

| S. No. | NDC | Pack Size | Batch # | Expiry |
|---------------|--------------|------------------|----------------|---------------|
| 1. | 68462-534-35 | 30 G | 15200058 | 06/2022 |
| 2. | 68462-534-94 | 100 G | 15200065 | 06/2022 |
| 3. | 68462-534-35 | 30 G | 15200066 | 06/2022 |
| 4. | 68462-534-35 | 30 G | 15200067 | 06/2022 |
| 5. | 68462-534-35 | 30 G | 15200075 | 07/2022 |
| 6. | 68462-534-65 | 60 G | 15200092 | 08/2022 |
| 7. | 68462-534-35 | 30 G | 15200094 | 08/2022 |
| 8. | 68462-534-94 | 100 G | 15200108 | 09/2022 |
| 9. | 68462-534-94 | 100 G | 15200109 | 09/2022 |
| 10. | 68462-534-65 | 60 G | 15200114 | 09/2022 |
| 11. | 68462-534-65 | 60 G | 15200115 | 09/2022 |
| 12. | 68462-534-35 | 30 G | 15200119 | 09/2022 |
| 13. | 68462-534-35 | 30 G | 15200120 | 09/2022 |
| 14. | 68462-534-35 | 30 G | 15200122 | 09/2022 |
| 15. | 68462-534-65 | 60 G | 15200123 | 10/2022 |
| 16. | 68462-534-65 | 60 G | 15200124 | 10/2022 |
| 17. | 68462-534-94 | 100 G | 15200125 | 10/2022 |

| S. No. | NDC | Pack Size | Batch # | Expiry |
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| 18. | 68462-534-35 | 30 G | 15200131 | 10/2022 |
| 19. | 68462-534-35 | 30 G | 15200132 | 10/2022 |
| 20. | 68462-534-35 | 30 G | 15200133 | 11/2022 |
| 21. | 68462-534-35 | 30 G | 15200134 | 11/2022 |
| 22. | 68462-534-35 | 30 G | 15200136 | 11/2022 |
| 23. | 68462-534-35 | 30 G | 15200139 | 11/2022 |
| 24. | 68462-534-65 | 60 G | 15200142 | 11/2022 |
| 25. | 68462-534-65 | 60 G | 15200144 | 11/2022 |
| 26. | 68462-534-94 | 100 G | 15200148 | 11/2022 |
| 27. | 68462-534-94 | 100 G | 15200149 | 11/2022 |
| 28. | 68462-534-94 | 100 G | 15200150 | 11/2022 |
| 29. | 68462-534-94 | 100 G | 15210007 | 12/2022 |
| 30. | 68462-534-94 | 100 G | 15210009 | 12/2022 |
| 31. | 68462-534-94 | 100 G | 15210012 | 12/2022 |
| 32. | 68462-534-65 | 60 G | 15210014 | 12/2022 |
| 33. | 68462-534-65 | 60 G | 15210015 | 12/2022 |
| 34. | 68462-534-94 | 100 G | 15210018 | 12/2022 |
| 35. | 68462-534-65 | 60 G | 15210021 | 12/2022 |
| 36. | 68462-534-65 | 60 G | 15210031 | 01/2023 |
| 37. | 68462-534-35 | 30 G | 15210033 | 01/2023 |
| 38. | 68462-534-35 | 30 G | 15210035 | 01/2023 |
| 39. | 68462-534-35 | 30 G | 15210036 | 01/2023 |
| 40. | 68462-534-35 | 30 G | 15210038 | 01/2023 |
| 41. | 68462-534-94 | 100 G | 15210049 | 02/2023 |

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| 42. | 68462-534-65 | 60 G | 15210055 | 02/2023 |
| 43. | 68462-534-65 | 60 G | 15210073 | 03/2023 |
| 44. | 68462-534-65 | 60 G | 15210075 | 03/2023 |
| 45. | 68462-534-94 | 100 G | 15210076 | 03/2023 |
| 46. | 68462-534-94 | 100 G | 15210077 | 03/2023 |
| 47. | 68462-534-94 | 100 G | 15210089 | 03/2023 |
| 48. | 68462-534-35 | 30 G | 15210092 | 03/2023 |
| 49. | 68462-534-35 | 30 G | 15210094 | 03/2023 |
| 50. | 68462-534-35 | 30 G | 15210097 | 03/2023 |
| 51. | 68462-534-35 | 30 G | 15210099 | 03/2023 |
| 52. | 68462-534-35 | 30 G | 15210100 | 04/2023 |
| 53. | 68462-534-35 | 30 G | 15210101 | 04/2023 |
| 54. | 68462-534-35 | 30 G | 15210104 | 04/2023 |
| 55. | 68462-534-94 | 100 G | 15210112 | 04/2023 |
| 56. | 68462-534-94 | 100 G | 15210114 | 04/2023 |
| 57. | 68462-534-65 | 60 G | 15210117 | 04/2023 |
| 58. | 68462-534-65 | 60 G | 15210118 | 04/2023 |
| 59. | 68462-534-35 | 30 G | 15210122 | 05/2023 |
| 60. | 68462-534-94 | 100 G | 15210124 | 05/2023 |
| 61. | 68462-534-94 | 100 G | 15210125 | 05/2023 |
| 62. | 68462-534-94 | 100 G | 15210127 | 05/2023 |
| 63. | 68462-534-65 | 60 G | 15210144 | 06/2023 |
| 64. | 68462-534-65 | 60 G | 15210147 | 06/2023 |
| 65. | 68462-534-35 | 30 G | 15210148 | 06/2023 |

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| 66. | 68462-534-35 | 30 G | 15210149 | 06/2023 |
| 67. | 68462-534-35 | 30 G | 15210153 | 06/2023 |
| 68. | 68462-534-35 | 30 G | 15210155 | 06/2023 |
| 69. | 68462-534-35 | 30 G | 15210157 | 06/2023 |
| 70. | 68462-534-35 | 30 G | 15210158 | 06/2023 |
| 71. | 68462-534-65 | 60 G | 15210160 | 06/2023 |
| 72. | 68462-534-65 | 60 G | 15210162 | 06/2023 |
| 73. | 68462-534-94 | 100 G | 15210169 | 07/2023 |
| 74. | 68462-534-94 | 100 G | 15210170 | 07/2023 |
| 75. | 68462-534-65 | 60 G | 15210171 | 07/2023 |
| 76. | 68462-534-35 | 30 G | 15210173 | 07/2023 |
| 77. | 68462-534-35 | 30 G | 15210174 | 07/2023 |
| 78. | 68462-534-35 | 30 G | 15210176 | 07/2023 |
| 79. | 68462-534-35 | 30 G | 15210177 | 07/2023 |
| 80. | 68462-534-35 | 30 G | 15210178 | 07/2023 |
| 81. | 68462-534-35 | 30 G | 15210179 | 07/2023 |
| 82. | 68462-534-35 | 30 G | 15210184 | 08/2023 |
| 83. | 68462-534-35 | 30 G | 15210186 | 08/2023 |
| 84. | 68462-534-65 | 60 G | 15210187 | 08/2023 |
| 85. | 68462-534-65 | 60 G | 15210190 | 08/2023 |
| 86. | 68462-534-65 | 60 G | 15210191 | 08/2023 |
| 87. | 68462-534-65 | 60 G | 15210193 | 08/2023 |
| 88. | 68462-534-94 | 100 G | 15210196 | 08/2023 |
| 89. | 68462-534-94 | 100 G | 15210199 | 08/2023 |

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|--------|--------------|-----------|----------|---------|
| 90. | 68462-534-94 | 100 G | 15210204 | 09/2023 |
| 91. | 68462-534-94 | 100 G | 15210206 | 09/2023 |
| 92. | 68462-534-94 | 100 G | 15210207 | 09/2023 |
| 93. | 68462-534-94 | 100 G | 15210210 | 09/2023 |
| 94. | 68462-534-65 | 60 G | 15210212 | 09/2023 |
| 95. | 68462-534-35 | 30 G | 15210214 | 09/2023 |
| 96. | 68462-534-35 | 30 G | 15210225 | 10/2023 |
| 97. | 68462-534-35 | 30 G | 15210226 | 10/2023 |
| 98. | 68462-534-35 | 30 G | 15210228 | 10/2023 |
| 99. | 68462-534-35 | 30 G | 15210230 | 10/2023 |
| 100. | 68462-534-35 | 30 G | 15210231 | 10/2023 |
| 101. | 68462-534-65 | 60 G | 15210244 | 11/2023 |
| 102. | 68462-534-65 | 60 G | 15210247 | 11/2023 |
| 103. | 68462-534-94 | 100 G | 15210248 | 11/2023 |
| 104. | 68462-534-94 | 100 G | 15220004 | 12/2023 |
| 105. | 68462-534-65 | 60 G | 15220007 | 12/2023 |
| 106. | 68462-534-94 | 100 G | 15220013 | 12/2023 |
| 107. | 68462-534-94 | 100 G | 15220014 | 12/2023 |
| 108. | 68462-534-94 | 100 G | 15220015 | 12/2023 |
| 109. | 68462-534-65 | 60 G | 15220019 | 01/2024 |
| 110. | 68462-534-94 | 100 G | 15220025 | 01/2024 |
| 111. | 68462-534-94 | 100 G | 15220026 | 01/2024 |
| 112. | 68462-534-65 | 60 G | 15220028 | 01/2024 |
| 113. | 68462-534-65 | 60 G | 15220032 | 02/2024 |

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| 114. | 68462-534-65 | 60 G | 15220034 | 02/2024 |
| 115. | 68462-534-65 | 60 G | 15220053 | 02/2024 |
| 116. | 68462-534-65 | 60 G | 15220062 | 03/2024 |
| 117. | 68462-534-65 | 60 G | 15220064 | 03/2024 |
| 118. | 68462-534-65 | 60 G | 15220072 | 03/2024 |
| 119. | 68462-534-35 | 30 G | 15220001 | 12/2023 |
| 120. | 68462-534-35 | 30 G | 15220002 | 12/2023 |

Recall of this batch has been initiated due to the complaints of ‘tube split from side seam’.

See details of product batches listed in above table and refer enclosed product labels for ease in identifying the product.

Examine your inventory and if you have any batches specified in above table then quarantine it immediately.

We are requesting the batch specified in the above table to be returned to Qualanex, LLC (address below) using the Postage Paid Product Return label that was provided in your Recall Return Packet.

Qualanex, LLC
1410 Harris Road
Libertyville, IL 60048

See enclosed product labels for ease in identifying the product at wholesaler levels.

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 847-737-3719 or email to recall@qualanex.com.

If you have any questions regarding your recall return please contact Qualanex at 800-505-9291.

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

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Zhi Chen

Associate Director, Regulatory Affairs

Tel.: (201) 331-4238

Fax: (201) 831-0080

Email: Zhi.chen@glenmarkpharma

Enclosure(s):

Product Labels

Recall Return Response Form