

# **Medicine Quality Alert: Class II Recall of several batches of Tenofovir Disoproxil Fumarate /Lamivudine/ Dolutegravir (300/300/50mg) manufactured by Universal Corporation Ltd**

Universal Corporation Ltd has initiated a voluntary recall of specific batches of Tenofovir Disoproxil Fumarate/Lamivudine/Dolutegravir tablets due to discoloration of the induction seals, black spots on the tablets, and cracked tablets.

From: Pharmacy and Poisons Board  
Published: 07 December 2022

**Recall Reference Number:** REC/2022/09

**Recall Classification:** Class II

**Recall Level:** Retail/Facility Level

**Company Name:** Universal Corporation Ltd, Kenya

**Product name:** Tenofovir Disoproxil Fumarate/Lamivudine/Dolutegravir

**Active Pharmaceutical Ingredient:** Tenofovir Disoproxil Fumarate/Lamivudine/Dolutegravir (300/300/50mg)

## **Affected Batches**

|     | <b>Batch No</b> | <b>Manufacture Date</b> | <b>Expiry Date</b> | <b>Pack Size</b> |
|-----|-----------------|-------------------------|--------------------|------------------|
| 1.  | 5810848         | 20.05.2022              | 30.04.2024         | 90's             |
| 2.  | 5810847         | 01.04.2022              | 31.03.2024         | 90's             |
| 3.  | 5810846         | 16.05.2022              | 30.04.2024         | 90's             |
| 4.  | 5810845         | 14.04.2022              | 31.03.2024         | 90's             |
| 5.  | 5810844         | 16.05.2022              | 30.04.2024         | 90's             |
| 6.  | 5810833         | 11.05.2022              | 30.04.2024         | 90's             |
| 7.  | 5810832         | 04.05.2022              | 30.04.2024         | 90's             |
| 8.  | 5810831         | 01.05.2022              | 30.04.2024         | 90's             |
| 9.  | 5810830         | 02.05.2022              | 30.04.2024         | 90's             |
| 10. | 5810611         | 21.03.2022              | 29.02.2024         | 90's             |
| 11. | 5810612         | 25.03.2022              | 29.02.2024         | 90's             |
| 12. | 5810760         | 14.04.2022              | 31.03.2024         | 90's             |
| 13. | 5810761         | 14.04.2022              | 31.03.2024         | 90's             |
| 14. | 5810762         | 16.04.2022              | 31.03.2024         | 90's             |
| 15. | 5810763         | 01.04.2022              | 31.03.2024         | 90's             |
| 16. | 5810764         | 01.04.2022              | 31.03.2024         | 90's             |
| 17. | 5810797         | 02.05.2022              | 30.04.2024         | 90's             |
| 18. | 5810798         | 02.05.2022              | 30.04.2024         | 90's             |
| 19. | 5810799         | 01.05.2022              | 30.04.2024         | 90's             |

|     |         |            |            |      |
|-----|---------|------------|------------|------|
| 20. | 5810800 | 04.05.2022 | 30.04.2024 | 90's |
| 21. | 5810801 | 04.05.2022 | 30.04.2024 | 90's |
| 22. | 5810812 | 14.04.2022 | 31.03.2024 | 90's |
| 23. | 5810813 | 14.04.2022 | 31.03.2024 | 90's |
| 24. | 5810814 | 16.04.2022 | 31.03.2024 | 90's |
| 25. | 5810815 | 01.04.2022 | 31.03.2024 | 90's |
| 26. | 5810816 | 01.05.2022 | 30.04.2024 | 90's |
| 27. | 5810829 | 02.05.2022 | 30.04.2024 | 90's |
| 28. | 5809767 | 01.08.2021 | 31.07.2023 | 90's |
| 29. | 5809768 | 20.08.2021 | 31.07.2023 | 90's |
| 30. | 5810264 | 01.01.2022 | 31.12.2023 | 90's |
| 31. | 5810859 | 24.05.2022 | 30.04.2024 | 90's |
| 32. | 5810860 | 24.05.2022 | 30.04.2024 | 90's |
| 33. | 5810861 | 24.05.2022 | 30.04.2024 | 90's |
| 34. | 5810862 | 21.03.2022 | 29.02.2024 | 90's |
| 35. | 5810863 | 26.05.2022 | 30.04.2024 | 90's |
| 36. | 5810922 | 14.04.2022 | 31.03.2024 | 90's |
| 37. | 5810923 | 01.05.2022 | 30.04.2024 | 90's |
| 38. | 5810924 | 01.06.2022 | 31.05.2024 | 90's |
| 39. | 5810935 | 01.04.2022 | 31.03.2024 | 90's |
| 40. | 5810936 | 01.04.2022 | 31.03.2024 | 90's |
| 41. | 5810937 | 02.05.2022 | 30.04.2024 | 90's |
| 42. | 5810938 | 01.06.2022 | 31.05.2024 | 90's |
| 43. | 5810939 | 08.06.2022 | 31.05.2024 | 90's |
| 44. | 5810950 | 08.06.2022 | 31.05.2024 | 90's |
| 45. | 5810951 | 13.06.2022 | 31.05.2024 | 90's |
| 46. | 5810952 | 13.06.2022 | 31.05.2024 | 90's |
| 47. | 5810953 | 13.06.2022 | 31.05.2024 | 90's |
| 48. | 5810954 | 13.06.2022 | 31.05.2024 | 90's |
| 49. | 5810973 | 13.06.2022 | 31.05.2024 | 90's |
| 50. | 5810974 | 01.05.2022 | 30.04.2024 | 90's |
| 51. | 5810975 | 02.05.2022 | 30.04.2024 | 90's |
| 52. | 5810976 | 02.05.2022 | 30.04.2024 | 90's |
| 53. | 5810977 | 01.05.2022 | 30.04.2024 | 90's |
| 54. | 5810983 | 04.05.2022 | 30.04.2024 | 90's |
| 55. | 5811074 | 04.05.2022 | 30.04.2024 | 90's |
| 56. | 5811075 | 14.04.2022 | 31.03.2024 | 90's |
| 57. | 5811076 | 14.04.2022 | 31.03.2024 | 90's |
| 58. | 5811077 | 16.04.2022 | 31.03.2024 | 90's |
| 59. | 5811078 | 01.04.2022 | 31.03.2024 | 90's |
| 60. | 5811079 | 01.06.2022 | 31.05.2024 | 90's |
| 61. | 5810920 | 31.05.2022 | 30.04.2024 | 30's |
| 62. | 5810921 | 31.05.2022 | 30.04.2024 | 30's |
| 63. | 5810922 | 31.05.2022 | 30.04.2024 | 30's |
| 64. | 5809767 | 01.08.2021 | 31.07.2023 | 30's |

|     |         |            |            |      |
|-----|---------|------------|------------|------|
| 65. | 5809768 | 20.08.2021 | 31.07.2023 | 30's |
| 66. | 5810905 | 27.05.2022 | 30.04.2024 | 30's |
| 67. | 5810906 | 27.05.2022 | 30.04.2024 | 30's |
| 68. | 5810907 | 30.05.2022 | 30.04.2024 | 30's |
| 69. | 5810908 | 31.05.2022 | 30.04.2024 | 30's |
| 70. | 5810909 | 31.05.2022 | 30.04.2024 | 30's |

### **Brief description of the problem**

Universal Corporation Ltd has initiated a voluntary recall of the affected batches of Tenofovir Disoproxil Fumarate/Lamivudine/Dolutegravir up to the retail/hospital pharmacy level. The product is being recalled due to several market complaints of discolored induction seals, black spots, and cracked tablets.

### **Action for healthcare professionals**

You are advised to immediately quarantine and stop supplying all remaining stock of the affected batches of the product. Universal Corporation Ltd will contact you to arrange the return of the impacted batches of the product.

### **Action for patients and caregivers**

Patients who have been prescribed the impacted patients should seek medical advice from healthcare providers.

### **Further Information**

For stock inquiries please contact Universal Corporation Limited by email: [info@ucl.co.ke](mailto:info@ucl.co.ke) or via telephone on +254 722707126, +254 721922280, +254 734513075, +254 738279223, +254 738279224, +254(0) 202693836, +254(0) 202693835, +254(0) 202693834

You are encouraged to promptly report any cases of adverse reactions and suspected substandard or falsified products to the nearest healthcare facility or through the following channels:

- <https://pv.pharmacyboardkenya.org/users/mpublic>
- USSD code at \*271#
- Email [pv@ppb.go.ke](mailto:pv@ppb.go.ke) or [pms@ppb.go.ke](mailto:pms@ppb.go.ke)
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further information please contact the Pharmacy and Poisons Board by email: [pms@ppb.go.ke](mailto:pms@ppb.go.ke)