

All correspondence should be addressed to the Director General



In reply, please quote

# ZAMBIA MEDICINES REGULATORY AUTHORITY

## PUBLIC NOTICE

Date: 14<sup>th</sup> July, 2023

To: Distributors, Wholesalers, Retailers, Health Facilities, Healthcare Professionals, General Public

### **MEDICAL PRODUCT ALERT: RECALL OF ALL MEDICINES MANUFACTURED BY LEBEN LABORATORIES PRIVATE LIMITED, INDIA FROM THE ZAMBIAN MARKET**

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the laws of Zambia. The main mandate of ZAMRA is to regulate, and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances for human and animal use for public health protection.

The Authority wishes to notify healthcare professionals and the general public that it has **suspended Marketing Authorisations (MAs)** for all medicines and allied substances manufactured by **Leben Laboratories Private Limited, India** (*See attached list for ease of reference*). This suspension of the MAs is as a result of product quality problems and failure by the facility to comply with the World Health Organisation's current Good Manufacturing Practices (cGMP) Guidelines. Based on this, the quality, safety and efficacy of products from this manufacturer is not guaranteed.

Therefore, the Authority has suspended MAs for **ALL** medicines and allied substances manufactured by Leben Laboratories Pvt. Limited, India for **twenty-four (24) months**. In this period, no products manufactured by Leben Laboratories Private Limited, India will be allowed in Zambia.

In view of the above, all health facilities, pharmaceutical outlets and members of the public in possession of any product manufactured by Leben Laboratories Private Limited, India are advised to stop distribution, dispensing or using these products and return them to their supplier for replacement with better quality assured products. Importers of these products have been directed to initiate the withdraw of these products from the market and plan for their safe disposal.

The Authority has heightened its post market surveillance activities for these products and will closely monitor the withdraw process to ensure that the products are completely removed from circulation in the interest of public health.

Should the public need further clarification, please do not hesitate to contact the undersigned.

Makomani Siyanga (Mr)  
**DIRECTOR-GENERAL**

List of products withdrawn from the market

<b>S/N</b>	<b>Name of Product(s)</b>	<b>Application No.</b>	<b>Marketing Authorisation No.</b>
1.	Libitus LS Syrup	10400/15	149/087
2.	Cypine Tablets	10401/15	228/073
3.	Alwo 400 Tablets	10403/15	149/088
4.	Ibuplus Tablets	10404/15	228/072
5.	Sinurho Suspension	10583/15	228/069
6.	Beclomin Lotion	10584/15	228/070
7.	Alclox Capsules	1540/02	149/008
8.	Alclox Suspension	1541/02	149/043
9.	Amphen Capsules	1542/02	149/007
10.	Antagit-DS Gel	1544/02	149/042
11.	Ateleb 100mg Tablets	1547/02	149/012
12.	Beclomin Ointment	1548/02	149/031
13.	Cipium Tablets	1549/02	149/002
14.	Ciproleb 500 Tablets	1550/02	149/019
15.	Q.S.M Tablets	1551/02	149/061
16.	Hykophos Syrup	1552/02	149/055
17.	Moxileb Dry Syrup	1554/02	149/001
18.	Moxileb 250mg Capsules	1555/02	149/004
19.	Ateleb 50mg Tablets	1556/02	149/013
20.	Adiflam Plus Tablets	1576/02	149/070
21.	Adiflam Compound Tablets	1577/02	149/069
22.	Foliben Tablet	1578/02	149/023
23.	Ciproleb 250 Tablets	1579/02	149/071
24.	Indul 25mg Capsules	1580/02	149/018
25.	Ibut 200mg Tablets	1581/02	149/020
26.	Kelvin Syrup	1582/02	149/041
27.	Kelvin Tablets	1583/02	149/025

<b>S/N</b>	<b>Name of Product(s)</b>	<b>Application No.</b>	<b>Marketing Authorisation No.</b>
28.	Promethazine Syrup	1588/02	149/030
29.	Promezin Tablet	1589/02	149/021
30.	Lebasma-4 Tablets	1590/02	149/029
31.	Lebasma Syrup	1591/02	149/028
32.	Silveleb 1% Cream	1592/02	149/014
33.	Tetret-250mg Capsules	1593/02	149/017
34.	Zylo-P Solution	1594/02	149/022
35.	Benzyl Benzoate Application	1809/02	149/016
36.	Cexil 500mg Tablets	1810/02	149/056
37.	Chlorpromazine 25mg Tablets	1811/02	149/057
38.	Chelferron Liquid	1812/02	149/059
39.	Griseben 125mg Tablets	1814/02	149/010
40.	Kelvin-P Syrup	1815/02	149/068
41.	Nalix Tablet	1819/02	149/005
42.	Arteflo-40 Tablet	1820/02	149/011
43.	Sinurhon Tablets	1821/02	149/077
44.	Scabcur Lotion	1822/02	149/015
45.	Cexil Syrup	1923/02	149/054
46.	Lampy-250 Capsules	1927/02	149/035
47.	Regurg Tablet	1928/02	149/003
48.	Zinectil-100 Tablets	2515/04	149/033
49.	Haloperidol Tablets	2516/04	149/058
50.	QSM Suspension	2518/04	149/024
51.	Trifluoperazine Tablets	2520/04	149/006
52.	Prohibin Capsules	2771/04	149/040
53.	Cebay-Trx-1000 Injection	2772/04	149/038
54.	Cefaxil-1000 Injection	2773/04	149/039
55.	Cipium Syrup	2774/04	149/037

<b>S/N</b>	<b>Name of Product(s)</b>	<b>Application No.</b>	<b>Marketing Authorisation No.</b>
56.	Adiflam Injection	3531/05	149/044
57.	Cortileb Cream	3532/05	149/045
58.	Elcuf Syrup	3533/05	149/046
59.	Enderm G.M Cream	3534/05	149/047
60.	Nystaleb Suspension	3535/05	149/048
61.	Pyraleb Suspension	3536/05	149/050
62.	Pyraleb Tablets	3537/05	149/052
63.	Zylo-P Ointment	3538/05	149/051
64.	Betaleb Ointment	3813/06	149/067
65.	Amileb-25 Tablet	4413/07	149/066
66.	Cebay - TRX 250 Injection	4414/07	149/062
67.	Cebay 100 Dry Powder	4415/07	149/064
68.	Lebasma 2 Tablets	4416/07	149/063
69.	PZQ Tablet	4417/07	149/065
70.	Lamizol O Tablets	4571/07	149/074
71.	Lamizol O Suspension	4572/07	149/073
72.	Ferrous Sulphate Tablets	4756/07	149/075
73.	Multivitamins Tablets	4757/07	149/076
74.	Adiflam -SR Tablets	7850/13	149/078
75.	Rihaee Tablets	7906/12	149/083
76.	Kaldol Suspension	9054/14	149/080
77.	Moxileb CV 228.5 Dry Syrup	9055/14	149/081
78.	Fricold Suspension	9057/14	149/079
79.	Libitus Cough Syrup	9058/14	149/082
80.	Colicspam Oral Drops	9059/14	149/084
81.	Colicspam Oral Suspension	9060/14	149/085
82.	Betalab Cream	9394/14	149/091
83.	Enderm Cream	9395/14	149/092

<b>S/N</b>	<b>Name of Product(s)</b>	<b>Application No.</b>	<b>Marketing Authorisation No.</b>
84.	Azileb 200 Suspension	9396/14	149/089
85.	Azileb 500 Tablets	9397/14	149/090
86.	HCT Tablets	9873/14	228/071
87.	Adiflam Plus Suspension	9980/15	149/086