

# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control  
MUSCAT



سِلاطِنَا حَمَانَا  
وَزَارَةُ الصِّحَّةِ  
المديرية العامة للصحة  
والرقابة الدوائية  
مسقط

TO:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies, MOH

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Director General of Primary Health Care, MOH

Director General of Specialised Medical Care, MOH

Director General of Quality Assurance Centre, MOH

Director of Rational Drug Use

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 63/2021 dated 30.3.2021  
regarding Product Recall (Class III) of LORINASE 5MG/120MG TABLETS.

(Mfr: SPIMACO/KSA)

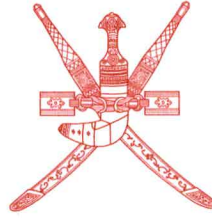
Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Section Head (Drug Information)

# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control  
MUSCAT



سلطنة عمان  
وزارة الصحة  
المديرية العامة للأدوية  
والرقابة الدوائية  
مسقط

Circular No. 63 /2021

16 -08-1442 H

30 -03-2021

## سحب دواء / Product Recall

### LORINASE 5mg/120mg Tablets

Recall	Class III	تصنيف السحب
Recall level	Retail level	مستوى السحب
Product Information		معلومات المستحضر
Product Name	LORINASE Tablets	اسم المستحضر
Active Ingredient(s)	Loratidine 5mg, Pseudoephedrine 120mg	المادة الفعالة
Batch Details	All Batches	تفاصيل التشغيل
Manufacturer	SPIMACO - Saudi Arabia	الشركة المصنعة
Local Agent	Muscat Pharmacy	الوكيل المحلي
Reason for Recall		سبب السحب
The products recalled in its country of origin due to noncompliance to bioequivalent study with the reference product.	بسبب قيام بلد المنشأ بسحب جميع تشغيلات الدواء المذكور اعلاه ، وذلك لعدم تكافئه حيويًا مع المستحضر المرجعي.	
Recommendation		التوصيات
M/S: Muscat Pharmacy - To arrange recall of the above batch and follow Circular No. 73/2019 (Guideline for Medicines & Pharmaceutical Products Recall Procedure)	على الوكيل المحلي (صيدلية مسقط) : إتخاذ اللازم لسحب التشغيلة المذكورة، وإتباع التعليمات الخاصة بالسحب كما جاء في التعميم رقم 2019/73 (دليل سحب الأدوية والمستحضرات الصيدلانية)	

Dr. Mohammed Hamdan Al Rubaie  
Director General

