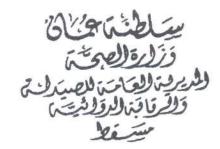
## Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control

#### **MUSCAT**





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

A C	0	
Aller	Com	pliments,
TALCUL	COLLI	Pilling

Please find attached our Circular No.	25	dated	07/02/2	-
regarding voluntary recall of certain pl	harmaceutical	products from	Julphar/UAE.	2

#### 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** 



سيرلطنگا پي کاک وَزَلِرَوَالِعِهِی والديرهِ دَالِعَامَ دَالعِسَرالِ جَ وَالْفِرِوَا لِبَدَالِدُوَلِ الْرُيَّةِ مَسِيرُ عَطْ

Circular No. 25/2021 24-06-1442 H 07-02-2021

### **Voluntary Recall**

### سحب طوعي

Recall	Class II		تصنيف السحب		
Recall level	Wholesale le	vel	مستوى السحب		
Product Information			معلومات المستحضر		
Product Name	Batch Details				
Mucolyte Syrup	All Batches				
Supraproct-S Suppositories		74			
Julmentin 375mg Tablets	1				
Butalin 2mg Tablet					
Butalin 4mg Tablet	1				
Julmentin Forte Tablets					
Scopinal Syrup	ī				
Lipigard 10mg Tablets	_				
Manufacturer	Julphar, UAE		الشركة المصنعة		
Local Agent	Scientific Phar	macy	الوكيل المحلي		
Reason for Recall			سبب السحب		
Voluntary Recall of all batches of above-mentioned products due to non-conformity to the stability specifications.			سحب طوعي لجميع التشغيلات للمنتجات المذكورة أعلاه ؛ وذلك لعدم مطابقتها للمواصفات المعتمدة من حيث دراسات الثباتية.		
Recommendation		15/2	التوصيات		
M/S: Scientific Pharmacy			على الوكيل المحلي (صيدلية العلمية ):		
- To arrange recall of the above batch and follow			اتخاذ اللازم لسحب التشغيلة المذكورة، وإتباع التعليمات		
Circular No. 73/2019 (Guideline for Medicines &		الخاصة بالسحب كما جاء في التعميم رقم 2019/73			
Circular No. 73/2019 (Guideline for	Medicines &	201	الخاصة بالسحب كما جاء في التعميم رقم 9/73		

Dr. Mohammed Hamdan Al Rubaie Director General



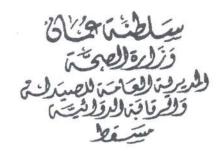
## Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control







Link to circular	https://www.moh.gov.om	n/en/web/dgpadc/-11	رابط التعميم		
Reporting ADR/Product defects/Medication errors  Department of Pharmacovigilance& Drug Information  Phone No: +968 22357686, 7687  Fax: +96822358489  web site:  https://www.moh.gov.om/en/ereporting-pharmacovigilance-department		/ مشاكل الجودة / الأخطاء	الإبلاغ عن الأثار العكسية للأدوية . الدوانية		
		رائرة التيقظ و المعلومات الدوائية هاتف رقم: 0096822357687/0096822357686 فاكس: 0096822358489 الموقع الإلكتروني: https://www.moh.gov.om/ar/-32			
Definition(s)			التعريفات		
Batch Recall			سحب تشغيلة:		
of a medicinal produc	twing specific batch/batches et from the distribution chain relating to deficiencies in efficacy.	باب تتعلق بجودة و سلامة و	لعمل على سحب تشغيلة أو تشغيلا لصيدلاني من سلسلة التوزيع لأس فعالية المستحضر الصيدلاني، ولا من نفس المستحضر		
Class II recall		la "	لسحب من الفئة الثانية:		
This recall occurs when product defects could cause illness or mistreatment, but are not Class I.		ددث هذا السحب عندما لا تسبب عيوب الدواء أو المستحضر صيدلاني المرض أو سوء العلاج ، ولكنها ليست بخطورة الفئة أولى.			
Retail Level recall  Include:  • All government institutions • Community positions • Healthcare positions • Wholesales			مستوى السحب (Retail) شمل: • جميع المؤسسات الصحي • صيدليات المجتمع • متخصصو الرعاية الصح		