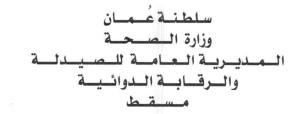
Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat





To:

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Establishments (to kindly arrange distribution to all Pvt. Health Institutions)

Director General of Health Services in all Governorates

Director of Rational Use of Medicine (MOH)

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

Director of Pharmacy & Medical Stores in all Governorate

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No: <u>50/2022</u> dated <u>21/03/2022</u> regarding Product Recall (Class III) of all batches of RABEZOLE 20MG E/C TABLETS from Jamjoom Pharmaceuticals, Saudi Arabia.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Supdt. of Central Drug Information
- Head of Cordn. & FU
- M/s. Ibn Sina Pharmacy to arrange recall and follow the procedures as stated in Circular No. 73/2019





Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat



سلطنة عُـمان وزارة الـصـحـة الـمـديـريـة العامـة للـصـيـدلـة والـرقـابـة الـدوائـيـة مـسـقـط



Circular No.50 /2022 \S -08-1443 H 2 \ -03-2022

Product Recall / سحب دواء

Rabezole 20mg E/C Tabs

Recall	Class III		11 :
Recall level	Retail leve		تصنيف السحب
	Actan level		مستوى السحب
Product Information			معلومات المستحضر
Product Name	Rabezole 20mg E/	C Tabe	
Active Ingredient(s)	Rabezole		اسم المستحضر
Batch Details			المادة الفعالة
D 200000	All Batches		تفاصيل التشغيلة
Manufacturer	Jamjoom Pharmaceuticals	- Saudi Arabia	الشركة المصنعة
Local Agent	Ibn Sina Pharmacy		
		lacy	الوكيل المحلي
Reason for Recall		**************************************	
	Extra 1 The Day of Land		سبب السحب
The product recalled in noncompliance to bioecomposition.	n its country of origin due to quivalence study with reference	محب جميع تشغيلات الدواء تكافؤه حيويا مع المستحضر	بسب قيام بلد المنشأ ب المذكور اعلاه ، وذلك لعده
Section Commencer			المرجعي.
Recommendation			المرجعي.

Dr. Mohammed Hamdan Al Rubaie

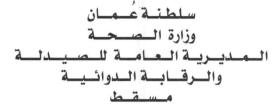




ص.ب: ۳۹۳ مسقط – الرمز البريدي: ۱۰۰ – هاتف: ۲۲۳۰۷۱۱۱ – فاکس: ۲۰۳۰ – P.O. Box: **393** Muscat - Postal Code : **100** - Tel: **22357111** - Fax: **22358489**

- Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat







Link to circular	https://www.moh.gov.om/en/web/dgpadc/-11		رابط التعميم
Reporting ADR/Product defects/Medication errors		[الاغ عن الأثار العكسية للأدوية / مشاكل الجودة الأخطاء الدوائية	
Department of Pharmacovigilance& Drug Information <i>Phone No:</i> +968 22357686, 7687		انرة التيقظ و المعلومات الدوائية هاتف رقم: ۱۳۵۲۲۳۵۷۲۸۲۳۰۷۲۸۲۲۳۵۷۲۸۲۳۰۷۲۸۲۳۵۷۲۸۲۳۵۷۲۸۲۳۵۷۲۸۲۳۵۷۲۸۲۳۵۷۲۸۲۳۵۷۲۸۲۳۵۷۲۸۲۳۵۷۲۸۲۳۵۷۰۸۷	
Fax: +96822358489 web site: https://www.moh.gov.om/en/ereporting-pharmacovigilance-department		فاكس: ۱۹۹۸۲۲۳۵۸٤۸۹ الموقع الإلكتروني: https://www.moh.gov.om/ar/-32	
Definition(s)			التعريفات
Product Recall The action of withdrawing all batches of a medicinal product from the distribution chain and users for reasons relating to deficiencies in the quality, safety or efficacy.		محب دواء: لعمل على سحب جميع التشغيلات من المستحضر الصيدلاني من سلسلة التوزيع لأسباب تتعلق بجودة و سلامة و فعالية لمستحضر الصيدلاني.	
Class III recall		السحب من القنة الثالثة:	
a significant har recall may be	urs when product defects may not pose azard to health i.e. low risk to health but initiated for other reasons, due to or efficacy concerns.	تشكل عيوب الدواء أو المستحضر لى الصحة، إلا أنه قد يتم السحب ودة أو السلامة أو الفعالية.	الصيدلاني خطرًا كبيرًا ع
Retail Level red	nall	Œ	مستوى السحب (Retail

Retail Level recall

Include:



All government and private health institutions

Community pharmacies

Healthcare professionals

May also include wholesales

جميع المؤسسات الصحية الحكومية والخاصة

صيدليات المجتمع

متخصصو الرعاية الصحية

وقد تشمل أيضا مستوى الجملة