



نتقدم بثقة  
Moving Forward  
with Confidence



To:

Pharmacist Incharge, Armed Forces Hospital (AT Khoudh & Salalah)  
Director of Pharmaceutical Care, Royal Hospital  
Director of Pharmaceutical Care, Khoula Hospital  
Pharmacist Incharge, Al Nahda Hospital  
Director of Pharmaceutical Care, DGHS, Muscat Governorate  
Director of Pharmaceutical Care, DGHS, Al Dakhliya Governorate  
Director of Pharmaceutical Care, DGHS, South Batinah Governorate  
Director of Pharmaceutical Care, DGHS, North Batinah Governorate  
Director of Pharmaceutical Care, DGHS, Al Dhahira Governorate  
Director of Pharmaceutical Care, DGHS, North Sharqiya Governorate  
Director of Pharmaceutical Care, DGHS, South Sharqiya Governorate  
Director of Pharmaceutical Care, DGHS, Musandam Governorate  
Director of Pharmaceutical Care, DGHS, Dhofar Governorate  
Director of Pharmaceutical Care, DGHS, Al Wusta Governorate  
Director of Pharmaceutical Care, DGHS, Buraimi Governorate  
Director of Pharmaceutical Care, DGMS  
Pharmacist Incharge, Al Massarah Hospital  
HOD, Pharmacy Department, Sultan Qaboos University Hospital  
Pharmacist Incharge, Royal Oman Police  
Pharmacist Incharge, The Diwan  
Pharmacist Incharge, The Sultan's Special Force  
Pharmacist Incharge, Internal Security Services  
Pharmacist Incharge, Petroleum Development of Oman  
Pharmacist Incharge, LNG Oman  
All Private Pharmacies & Drug Stores

After Compliments,

Kindly find attached our Circular No **62** dated **21/06/2026** Regarding Update to Health Care Professionals About Orlistat and Risk of Acute Kidney Injury and Kidney Stones.

Copy to:

- Director of Pharmacovigilance Department, DSC
- Director of Medicine Registration Department, DSC
- Director of Regulatory Compliance Department, DSC
- Director of Central Quality Control Lab., DSC
- Director of Medical Device Department, DSC
- Section Head of Medicine Safety Evaluation
- Section Head of Quality Problems and Medication Errors.
- Section Head of Pharmacovigilance
- Section Head of Clinical Trials



Circular No. 62 /2026

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21 -06-2026

### Subject: Orlistat and Risk of Acute Kidney Injury and Kidney Stones

The Drug Safety Center (DSC) would like to share new safety information published by the U.S. Food and Drug Administration (FDA) regarding Orlistat and the risk of acute kidney injury and kidney stones.

#### Orlistat and Renal Safety Concerns

**Orlistat** is a gastrointestinal lipase inhibitor indicated for weight management in overweight and obese patients.

Following a recent safety review, the FDA has approved updates to the product labeling for Orlistat to strengthen warnings regarding the **risk of hyperoxaluria, oxalate nephropathy, kidney stones, and acute kidney injury**. Patients with pre-existing kidney disease or a history of recurrent kidney stones may be at increased risk.

The **benefit-risk balance** of Orlistat remains **favorable** when used according to the approved prescribing information.

#### Advice for Healthcare Professionals:

- **Be aware of the risk** of hyperoxaluria, oxalate nephropathy, kidney stones, and acute kidney injury associated with Orlistat use.
- **Exercise caution** when prescribing Orlistat to patients with renal impairment or a history of kidney stones.
- **Advise patients to promptly report symptoms suggestive of renal complications**, including flank pain, hematuria, difficulty urinating, decreased urine output, or swelling of the lower extremities.
- **Consider discontinuation of Orlistat** if kidney injury is suspected and initiate appropriate clinical evaluation and management.
- **Monitor renal function** as clinically indicated, particularly in patients with underlying renal risk factors.





**Advice for Healthcare Professionals to Provide to Patients:**

- Inform your healthcare provider **before** using Orlistat if you have kidney disease or a history of kidney stones.
- **Seek medical attention immediately** if you experience severe back or flank pain, blood in the urine, difficulty passing urine, swelling of the legs or feet, or a decrease in urine output.
- **Do not stop or start** any medication without consulting your healthcare provider.

**Call to report:**

**Orlistat** is registered in Oman. All healthcare professionals, patients, and caregivers are requested to submit any adverse drug reactions through Ministry of Health e-portal to the Pharmacovigilance Department under the Drug Safety Center.



**Ph. Ibrahim Nasser Al Rashdi**  
Director General

