

نقدم 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 63 dated 23/06/2026 Regarding Update to Health Care Professionals About ACE-inhibitors: Be aware of the distinction between bradykinin- and histamine-mediated angioedema, as treatment strategies differ significantly.

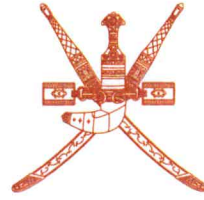
Copy to:

- 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



DSC
مركز سلامة الدواء
Drug Safety Center





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Circular No. **63**/2026

07 -01-1448 H
23 -06-2026

Subject: ACE-inhibitors: Be aware of the distinction between bradykinin- and histamine-mediated angioedema, as treatment strategies differ significantly

The Drug Safety Center (DSC) would like to share new safety information published by the Medicines and Healthcare products Regulatory Agency (MHRA) regarding **ACE-inhibitors: Be aware of the distinction between bradykinin- and histamine-mediated angioedema, as treatment strategies differ significantly.**

The product information for all ACE inhibitors is being updated to strengthen the warnings on the risk of delayed-onset angioedema, which may still occur after weeks to years of use. Healthcare professionals, particularly in emergency departments, should be aware of the potential for delayed onset of angioedema and the distinction between bradykinin- and histamine-mediated cases, as treatment strategies differ significantly and bradykinin mediated angioedema does not respond to standard treatment.

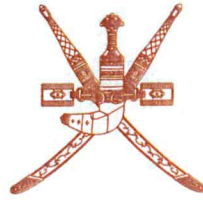
ACE inhibitors are indicated for the treatment of hypertension, heart failure, post myocardial infarction management, diabetic nephropathy, and cardiovascular risk reduction.

Angioedema is characterised by localised swelling of subcutaneous or submucosal tissues. Unlike histamine-mediated (allergic) angioedema, bradykinin-mediated angioedema usually occurs without urticaria and typically has a slower onset. Symptoms may involve the tongue, lips, and upper airway, and can be life-threatening.

Although uncommon or rare, ACE inhibitors are associated with both histamine-mediated and bradykinin-mediated angioedema. Certain populations, including older adults, women, people who smoke and patients of Black or African Caribbean ethnicity, may be at increased risk of angioedema.

Advice for Healthcare Professionals:

- **Angioedema** is a known uncommon or rare side-effect of ACE inhibitor treatment. This can either be allergic (histamine-mediated) or less commonly non-allergic (bradykinin-mediated). Healthcare professionals should consider bradykinin-mediated mechanisms as a cause when standard anaphylaxis treatment is ineffective
- **Angioedema** can occur at any time during treatment, including after weeks to years of use.
- **Swelling of the tongue, lip, face, or larynx** which may cause difficulty in breathing or swallowing may progress and can lead to **airway compromise**. Other symptoms can include gastrointestinal pain and cramps.
- Bradykinin-mediated angioedema is unlikely to respond to standard anaphylaxis treatments including adrenaline (epinephrine).
- Lack of response to standard anaphylaxis treatments should prompt consideration of bradykinin-mediated angioedema, with treatment informed by clinical protocols.
- If **angioedema** is suspected in a patient taking an ACE inhibitor, **discontinue** the ACE inhibitor immediately and **do not restart**.



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Advice for Healthcare Professionals to Provide to Patients:

- Although uncommon or rare, **angioedema** (swelling of the face, lips, tongue, or throat) can occur at any time while taking an ACE inhibitor, even if you have been taking it for a long period without problems.
- **Seek urgent medical attention** if you develop swelling of the face, lips, tongue, or throat, or experience difficulty breathing or swallowing whilst taking ACE inhibitors.
- **Do not take further doses** of your ACE inhibitor if angioedema is suspected and inform a healthcare professional immediately.
- **Inform healthcare professionals** if you have ever experienced angioedema, including while taking an ACE inhibitor. Please be aware that angioedema can occur for other reasons, and a healthcare professional may still recommend an ACE inhibitor for you in these instances.

Call to report:

ACE inhibitors are 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



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ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

✉ @DSCPHO Email: dscpho@moh.gov.om