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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

After Compliments,

Kindly find attached our Circular No **55** dated **25/05/2026** Regarding Update to Health Care Professionals About Amiodarone: reminder of risks of treatment and need for patient monitoring and supervision.

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



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Circular No. 55/2026

08 -12-1447 H
25 -05-2026

Subject: Amiodarone: reminder of risks of treatment and need for patient monitoring and supervision

The Drug Safety Center (DSC) would like to share a new safety information published by Medicine and Health products Regulatory Agency (MHRA) regarding Amiodarone: reminder of risks of treatment and need for patient monitoring and supervision.

Amiodarone is used to treat certain types of abnormal heart rhythm, including atrial fibrillation and tachyarrhythmias. Amiodarone is generally reserved for situations when other treatments cannot be used or have failed. Treatment should be initiated and monitored under hospital or specialist supervision and in accordance with clinical guidance.

Amiodarone has a long plasma half-life of around 50 days, meaning that any adverse effects may persist for a month (or more) after treatment has stopped.

Adverse effects of amiodarone on the lung:

Amiodarone can commonly cause lung inflammation (pneumonitis). In some cases, this inflammation can progress to more serious thickening or scarring (fibrosis), which can be life-threatening. Patients should be carefully evaluated clinically, and consideration given to chest X-rays before starting therapy. Symptoms of pulmonary toxicity can include shortness of breath (which may be severe and unexplained by the current cardiac status), non-productive cough, and general health deterioration (fatigue, weight loss, and fever).

Updated advice on lung imaging during amiodarone treatment:

Regular lung imaging during treatment may expose patients to excessive radiation, be alarming for patients, and was unnecessary given that patient-reported worsening of respiratory function is usually a good first indicator of pulmonary toxicity. For this reason, it is important that patients know the symptoms of pulmonary toxicity of which to be aware and the fact this can be serious and may happen at any time during treatment (or in the month after stopping treatment).

The Patient Information Leaflet is being updated to emphasise that respiratory symptoms may get progressively worse and can happen at any time after starting treatment. Additionally, the SmPC for healthcare professionals is being updated to emphasise that computerised tomography (CT) scans are more specific than X-rays and may be therefore more helpful in confirming a suspected diagnosis of lung toxicity.

Reminder on thyroid function monitoring:

Amiodarone treatment can commonly lead to hypothyroidism or hyperthyroidism, particularly in patients with a personal history of thyroid disorders in whom treatment is contraindicated. Thyroid-test levels should be checked before starting treatment, at 6- monthly intervals, and for several months following treatment discontinuation. Regular assessment is recommended in patients whose medical history indicates an increased risk of thyroid dysfunction.



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رؤية عمان
2040
Oman Vision

Advice for Healthcare Professionals:

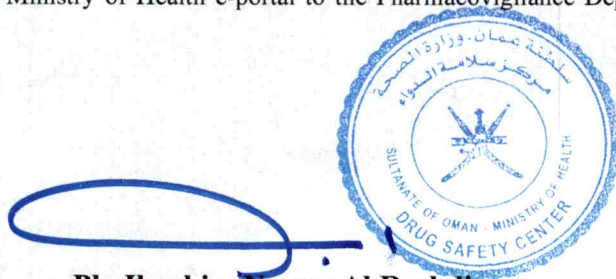
- **amiodarone** can cause **serious** adverse reactions affecting the eyes, heart, lung, liver, thyroid gland, skin, and peripheral nervous system.
- review **regularly** patients on **long-term** amiodarone treatment – some of these reactions may be **life-threatening** but onset can be delayed.
- check **liver and thyroid** function before treatment, and at 6-monthly intervals; thyroid function should also be monitored for several months after discontinuation.
- although routine **lung imaging** is not necessary in patients taking amiodarone long-term, make patients aware of the need to seek advice if they have new or worsening respiratory symptoms and consider using **computerised tomography (CT) scans** if pulmonary toxicity is suspected.

Advice for healthcare professionals to give to patients and carers:

- **amiodarone** is used to treat **serious** heart conditions in which your heart beats unevenly or too fast.
- always **read** the Patient Information Leaflet provided with your medicines and follow the advice on other medicines to avoid and what to do if you have a side effect.
- your doctor may perform **tests** of your blood, lungs, heartbeat, and eyes before and during treatment it's important to have these tests because they can identify if there's a problem.
- **stop taking amiodarone and see a doctor or go to a hospital straight away** if you experience any of the following **during treatment or in the period after stopping amiodarone**:
 - new or worsening shortness of breath or coughing that will not go away.
 - yellowing of the skin or eyes (jaundice), feeling tired or sick, loss of appetite, stomach pain, or high temperature.
 - weakness, weight loss or weight gain, heat or cold intolerance, hair thinning, sweating, changes in menstrual periods, swelling of the neck (goitre), nervousness, irritability, restlessness, or decreased concentration.

Call to report:

Amiodarone 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