



To:

Pharmacist Incharge, Armed Forces Hospital (Al Khoudh & Salalah)
Director of Pharmaceutical Care, Royal Hospital
Director of Pharmaceutical Care, Khoulia 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,

Please find attached our Circular No 128 dated 23/6/2025 regarding
Prolonged-Release Opioids: Removal of indication for relief of post-operative
pain.

Copy to:

- Director General, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Director Medical Device Control, DSC
- Supdt. of Central Drug Information
- Head of Cordn. & FU



Circular No. 128 / 2025

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27-12-1446 H
23-06-2025

Subject: Prolonged-release opioids: Removal of indication for relief of post-operative pain.

The Drug Safety Center (DSC) would like to share a new safety update published in Medicine and Healthcare Products Regulatory Agency (MHRA) website regarding Prolonged-release opioids: Removal of indication for relief of post-operative pain.

The indication for the treatment of post-operative pain has been removed from the licenses of all prolonged release opioids. These opioids should not be used postoperatively due to the increased risk of Persistent Post-Operative Opioid Use (PPOU) and opioid-induced ventilatory impairment (OIVI). It is not recommended to use transdermal patches for the treatment of post-operative pain.

Prolonged-release (modified release) opioids are indicated for moderate or severe pain and cancer pain, although NICE guidance [NG193] recommends that opioids are not used for chronic primary pain where there is no underlying condition accounting for the pain. A small number of prolonged release opioids containing morphine or oxycodone were also authorised for the treatment of post-operative pain, however concerns were raised on the potential for harm and an increased risk of PPOU and OIVI. PPOU is defined as continued opioid use beyond 90 days from the day of operation. Dependence is a well-known side effect of opioids.

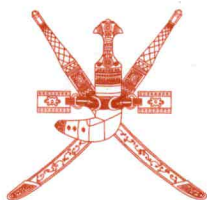


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Advice for Healthcare Professionals:

- Prolonged-release opioids provide relief from chronic severe pain, however, they should not be used for the treatment of acute pain following surgery.
- Prolonged-release opioids are associated with an increased risk of PPOU characterised as continued opioid use beyond 90 days following the operation, and an increased risk of OIVI causing serious respiratory depression, sedation, and depression of upper airway muscle tone.
- Before surgery, discuss with the patient the following:
 - Explain the risks of PPOU, dependence and potential risk of addiction and withdrawal reactions.
 - Explain the risk of OIVI especially for patients with underlying respiratory conditions.
 - Immediate-release opioids are used for short-term treatment of pain.
 - Discuss with the patient pain management strategies involving the use of immediate-release opioids and multimodal analgesia and plan for end of treatment.
- Patients whose pain is managed with opioids pre-operatively should have their treatment reviewed before and after surgery in line with Consensus Best Practice Guidelines.
- At discharge from hospital:
 - Only prescribe and supply a sufficient amount of immediate-release opioids to treat acute post-operative pain to minimise the risk of PPOU, dependence, stock piling of unused opioids and potential for diversion.
 - Communicate the pain management plan with the primary care practice taking over care in the community and document in patient clinical notes.
- It is important to report suspected dependence or respiratory depression to any medicine, including an opioid to DSC.



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Advice for Healthcare Professionals to Provide to Patients:

- Opioids provide relief from moderate to severe pain. Pain following an operation is usually short-lived and therefore should only require short-term treatment.
- Immediate release opioids are used for the treatment of short-term post-operative pain.
- If you are taking prolonged release opioids before going into hospital for an operation, talk to your doctor to discuss your pain management and ongoing needs
- There is a greater risk of respiratory depression (problems breathing) and persistent post-operative opioid use with prolonged release opioids.
- If you notice new or increased trouble with your breathing, Contact the nearest health center as this could be a sign of respiratory depression.
- If you feel like you cannot stop taking opioids as you had originally planned, contact your doctor as this could be a sign of Persistent Post-Operative Opioid Use (PPOU).

Post-operative pain prescribing recommendations:

Pain following surgery is usually short-lived, lasting between 5 – 7 days and therefore should only require short-term pain management best treated with immediate release opioids. However, many patients are discharged from hospitals with excessive amounts of opioids to meet their needs for acute post-operative pain management. This excess supply of opioids increases the risk of developing PPOU, dependence, addiction, or could lead to opioid diversion, and an increased risk of OIVI with unmanaged use. Therefore, patients should only be provided with a prescription for a sufficient amount of instant release opioids to manage their acute post-operative pain on discharge from hospital.



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Patients at increased risk:

Adjustments in dose or dosing regimen might be necessary in patients at increased risk of experiencing these severe adverse reactions, including patients:

- With compromised respiratory function or respiratory disease
- With neurological disease
- With renal impairment
- With cardiovascular disorders
- Using concomitant Central Nervous System (CNS) Depressants
- Older than 65 years
- With opioid tolerance
- Using opioids pre-operatively

Patients and healthcare professionals are encouraged to discuss treatment regimens and agree a post-operative pain management plan prior to the proposed surgical procedure.

Call to report:

Prolonged-release opioids are registered in Oman, healthcare professionals, patients, and caregivers are requested to submit adverse drug reaction reports to the pharmacovigilance and Drug Information Department in the DSC.

PH. IBRAHIM NASSER AL RASHDI
DIRECTOR GENERAL



DSC
مركز سلامة الدواء
Drug Safety Center



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

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