

<i>TAPENTADOL IS A HIGH RISK MEDICINE</i>	
USE WITH CAUTION AND ENSURE THE DIRECTIONS WITHIN THIS PROTOCOL ARE FOLLOWED CAREFULLY	
Areas where applicable	Hospital inpatients in general ward areas, excluding ICU/CCU/HDU and paediatrics
Authorised Prescribers	Consultant pain physicians, rehabilitation physicians and neurologists for initiation and titration. Medical officers for continuation.
Indications for use	Chronic moderate to severe disabling lower back, osteoarthritis and neuropathic pain unresponsive to non-narcotic analgesics, particularly in: <ul style="list-style-type: none"> • elderly with gastrointestinal side-effects • patients at high risk of serotonergic syndrome • patients with tendency to opioid side effects or where opioid adverse side-effects potentially detrimental, e.g. sleep apnoeic, respiratory depressed patients
Clinical condition	Chronic lower back pain, osteoarthritis or neuropathic pain unresponsive to non-narcotic analgesics (e.g. NSAIDs) or intolerant to strong opioids (e.g. nausea, vomiting, dizziness or constipation)
Contraindications	<ul style="list-style-type: none"> • Hypersensitivity to tapentadol or to any of the excipients • Significant respiratory depression, acute or severe bronchial asthma or hypercapnia • Actual or suspected paralytic ileus • Acute intoxication with alcohol, hypnotics, analgesics or psychotropic drugs • Concomitant monoamine oxidase inhibitor (MOAI) therapy or taken MOAI within the last 14 days • Head injury or increased intracranial pressure
Precautions	<ul style="list-style-type: none"> • Potential for abuse, misuse or diversion • Drug dependence - tolerance or withdrawal • Respiratory depression • Malignancy • Seizures • Severe renal impairment or moderate hepatic impairment • Biliary tract disease, including acute pancreatitis • Pregnancy (Category C) or lactation • Driving or use of machines
Place in therapy	2 nd line therapy after demonstrated ineffectiveness of non-narcotic analgesics or intolerance to opioids
Part of combination therapy, other drugs:	Antidepressants, anticonvulsants, gabapentin and paracetamol may be used in conjunction with tapentadol

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Tapentadol in
Moderate to Severe Chronic Pain



Important Safety Considerations	Tapentadol is available in both immediate release and sustained release formulations. The intended formulation must be clearly specified on the medication order by the prescriber. The labelling and packaging of the immediate and sustained release formulations are very similar. When supplying tapentadol products to inpatient areas, pharmacy should apply a dispensing label to the product highlighting the formulation type. Extreme care should be taken to ensure the correct product is selected when administering the drug.
Dosage	<p>The recommended dose of sustained release tapentadol (tapentadol SR) is 50 to 250 mg taken twice daily (100 to 500 mg per day) individualised according to pain severity, functional outcome, treatment response and side-effects.</p> <p>Immediate-release tapentadol (tapentadol IR) may be used for breakthrough pain in patients already established on the SR formulation. The recommended dose is 50 to 100mg four to six hourly.</p> <p>The total daily dose of tapentadol (both SR and IR formulations) should not exceed 500mg.</p> <p>Prior to cessation, dosage should be tapered every 3 days as appropriate. Gradual tapering is essential to prevent withdrawal symptoms.</p> <p>No dose adjustment is required in the elderly, mild hepatic or mild to moderate renal impairment.</p>
Duration of therapy	Tapentadol is initiated or maintained during the hospital admission. After discharge, the patient's GP will review the medication and continue if needed with supply external to the hospital system.
Important Drug Interactions	<p>Central nervous system depressants – other opioids, sedatives, hypnotics, CNS depressants or general anaesthetics may cause excessive respiratory depression and/or sedation.</p> <p>Monoamine Oxidase Inhibitors are contraindicated because of excessive noradrenaline reuptake inhibition causing tachycardia and hypertension.</p> <p>Monitor for serotonin syndrome in patients receiving serotonergic drugs, e.g. SSRI's, SNRIs, tricyclic antidepressants</p>
Prescribing Requirements	<p>All medication orders must be legible and clear indicating the full name of the prescribing doctor. All orders for tapentadol must include:</p> <ol style="list-style-type: none"> i. Drug and formulation (SR or IR) ii. Dose, route and frequency iii. Maximum daily dose for PRN orders iv. Indication
Administration Instructions	<p>Tapentadol SR is given twice daily</p> <p>Tapentadol IR is usually given 4 to 6 hourly PRN</p> <p>Both Tapentadol SR oral tablets Tapentadol IR oral tablets must be swallowed whole. Tapentadol can be administered with or without food.</p>

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Monitoring Requirements	<p>Monitor pain scores, functional and psychological assessment to assess response.</p> <p>Monitor for opioid-related adverse effects, including sedation, respiratory depression, constipation, nausea and pruritis, particularly during initiation and titration of therapy.</p> <p>Patient should be monitored in the pain or appropriate specialist clinic every 1 to 3 months during the maintenance phase of therapy.</p> <p>The risk of addiction should be discussed with the patient prior to initiation and the patient should be monitored for aberrant drug behaviours as part of specialist clinic reviews.</p>
Management of Complications	<p>Apply general supportive measures.</p> <p>In overdosage attempt to remove undigested drug from the gastrointestinal tract using activated charcoal.</p> <p>Respiratory depression should be treated with naloxone and maintenance of airway.</p>
Storage Requirements	<p>Where practicable tapentadol should be supplied from pharmacy on an individual patient basis and the patient's medication chart clinically reviewed by a pharmacist prior to supply.</p> <p>Tapentadol products must not be stored in clinical areas where use is infrequent. Any dispensed products that are no longer required should be removed from clinical areas at the earliest opportunity.</p>
Basis of Protocol/Guideline:	<p>PALEXIA® SR Product Information 5 November 2012 PALEXIA® IR Product Information September 2015 Rafael Galvez et al. Adv Ther 2013.DOI 10.1007/s/12325-013-0015-6 Richard C. Dart et al. J Opioid Management 2012; Novemebr/Decemebr. Steigerwald et al. CROM 2012;28(6):1-26 Wild JE et al. Pain Practice 2010;10(5):416-427. Buynak R et al. Expert Opinion. 2010;11(11):1787-1804 Joseph Pergolizzi et al. Pain Practice 2012;Vol 12(4): 290-306. Shane Kavanagh et al.Pain Medicine 2012;13:1110-1120 Lucy A Bee et al. Pain 2011;252:131-139.</p>
Groups consulted in development of this guideline	Pain specialists (POWH)
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