Prescribing Protocol SESLHDPR/587
Tapentadol in
Moderate to Severe Pain

Health
South Eastern Sydney
Local Health District

TAPENTADOL IS A HIGH RISK MEDICINE **USE WITH CAUTION AND ENSURE THE DIRECTIONS WITHIN THIS PROTOCOL ARE FOLLOWED CAREFULLY**	
Areas where applicable	Adult inpatients in all SESLHD facilities
Authorised Prescribers	Any prescriber may initiate tapentadol on the recommendation of a pain specialist, anaesthetist, rehabilitation physician, geriatrician, general physician, rheumatologist, neurologist or palliative care physician. All medical officers may continue existing therapy.
Indications for use	<u>Immediate release formulation:</u> Acute moderate to severe pain under the following circumstances: 1. As second line therapy after demonstrated ineffectiveness of other opioids, OR 2. First line in patients with an absolute or relative contraindication to other opioids, in particular: • elderly patients with gastrointestinal side-effects • patients at high risk of serotonergic syndrome • patients with tendency to opioid side effects or where opioid adverse side-effects are potentially detrimental, e.g. sleep apnoeic, respiratory depressed patients <u>Slow release formulation, with immediate release for breakthrough pain:</u> Slow release Tapentadol according to PBS restrictions. Chronic moderate to severe disabling pain unresponsive to non-narcotic analgesics, particularly in: • elderly patients with gastrointestinal side-effects • patients at high risk of serotonergic syndrome • patients with tendency to opioid side effects or where opioid adverse side-effects are potentially detrimental, e.g. sleep apnoeic, respiratory depressed patients
Clinical condition	Acute post-operative nociceptive and neuropathic pain, and acute severe non-operative pain (e.g. fractures) Chronic moderate to severe disabling lower back, osteoarthritis and neuropathic pain, unresponsive to non-narcotic analgesics (e.g. NSAIDs) or intolerant to strong opioids (e.g. nausea, vomiting, dizziness or constipation)

Contraindications	• 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 psychtropic drugs • Concomitant monoamine oxidase inhibitor (MOAI) therapy or taken MOAI within the last 14 days • Head injury or increased intracranial pressure
Precautions	• 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	Second line after demonstrated ineffectiveness of other opioids, or first line in patients with an intolerance or contraindication to other strong opioids on the recommendation of a pain specialist, anaesthetist or consultant recognised as an "Authorised Prescriber" (see above)
Part of combination therapy, other drugs:	Antidepressants, anticonvulsants, gabapentin and paracetamol may be used in conjunction with tapentadol
Important Safety Considerations	Tapentadol is available in both immediate release (IR) and sustained release (SR) formulations. The intended formulation must be clearly specified on the medication order by the prescriber. • For acute pain, only the ***IR*** formulation should be used. The naming, 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	Acute pain: Recommended dose of tapentadol *IR* is 50 to 100 mg four to six hourly **when required** (100 to 400mg per day). Dose should be individualised according to pain severity, functional outcome, treatment response and side-effects. Prior to cessation, tapering should be considered to prevent withdrawal symptoms. Chronic pain: Recommended dose of tapentadol *SR* is 50 to 250 mg twice daily (100 to 500 mg per day), individualised according to pain severity, functional outcome, treatment response and side-effects. Tapentadol *IR* may be used for breakthrough pain in patients established on the *SR* formulation. The recommended dose is 50 to 100 mg four to six hourly **when required**. Prior to cessation, dosage shoud be tapered every 3 days as appropriate. Gradual tapering is essential to prevent withdrawal symptoms. • The total daily dose of tapentadol (both SR and IR formulations) should not exceed 500 mg. • No dose adjustment is required in the elderly, mild hepatic or mild to moderate renal impairment.
Duration of therapy	Tapentadol is initiated or maintained during the hospital admission. Where initiated in hospital, prior to discharge the patient's home team is recommended to review a titration plan if deemed appropriate. After discharge, the patient's GP will review the medication and continue if needed with supply external to the hospital system.
Important Drug Interactions	Central nervous system depressants – other opioids, sedatives, hypnotics, CNS depressants or general anaesthetics may cause excessive respiratory depression and/or sedation. Monoamine Oxidase Inhibitors are contraindicated because of excessive noradrenaline reuptake inhibition causing tachycardia and hypertension. Monitor for serotonin syndrome in patients receiving serotonergic drugs, e.g. SSRI's, SNRIs, tricyclic antidepressants
Prescribing Requirements	All medication orders must be legible and clear indicating the full name of the prescribing doctor. All orders for tapentadol must include: i. Drug and formulation (SR or IR) ii. Dose, route and frequency iii. Maximum daily dose for PRN orders iv. Indication
Administration Instructions	Tapentadol *SR* is given twice daily Tapentadol *IR* is usually given every 4 to 6 hourly PRN Total daily dose (both IR and SR) not exceeding 500mg daily. Both Tapentadol IR and Tapentadol SR oral tablets must be swallowed whole. Tapentadol can be administered with or without food.

Monitoring Requirements	Monitor pain scores, functional and psychological assessment to assess response. Monitor for opioid-related adverse effects, including sedation, respiratory depression, constipation, nausea and pruritis, particularly during initiation and titration of therapy. For initiation for chronic pain: the patient should be monitored in the pain or appropriate specialist clinic every 1 to 3 months during the maintenance phase of therapy. 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.
Management of Complications	Apply general supportive measures. In overdosage, attempt to remove undigested drug from the gastrointestinal tract using activated charcoal. Respiratory depression should be treated with naloxone and maintenance of airway.
Storage Requirements	Where practicable, the patient's medication chart should be clinically reviewed by a pharmacist prior to the supply of tapentadol. Tapentadol products must not be stored in clinical areas where use is infrequent. Any tapentadol products that are no longer required should be removed from clinical areas at the earliest opportunity.
Basis of Protocol/Guideline:	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.
Groups consulted in development of this guideline	Pain specialists (POWH) Aged Care & Rehabilitation Clinical Stream (2018)

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GOVERNANCE	
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