

RCHT Guidelines for use of TAPENTADOL PR (Palexia SR)

Tapentadol SR is a drug combining two modes of action:

- Mu receptor agonist (like Morphine)
- Noradrenaline reuptake inhibition (like Duloxetine)

Tapentadol PR has a license for use in CHRONIC SEVERE PAIN.

In Cornwall it has been accepted for use in this condition IF MORPHINE RESULTS IN INADEQUATE THERAPEUTIC BENEFIT OR INTOLERABLE SIDE EFFECTS

Tapentadol PR prescription is to be initiated by SENIOR CLINICIANS only (in hospital or general practice). Trainees should not initiate Tapentadol without documented direct discussion with a consultant or GP.

We recommend:

Patients to be reviewed after a trial period, typically around one month, with the understanding that the drug will be stopped unless the patient reports CLEAR BENEFIT, with regards to pain, side effects and/or quality of life.

Current evidence suggests that, compared to current strong opioids (particularly oxycodone) Tapentadol demonstrates:

- Favourable gastrointestinal tolerability profile compared to oxycodoneⁱ or to oxycodone/naloxoneⁱⁱ
- Improved patient outcomes (Quality of life) compared to oxycodoneⁱ and to oxycodone/naloxoneⁱⁱ
- Improved neuropathic pain efficacy compared to oxycodoneⁱⁱⁱ and to oxycodone/naloxoneⁱⁱ

Conversion guidance for equianalgesia: Morphine oral 1: Tapentadol 2.5

Current opioid	Dose titration	Opioid dose	Tapentadol SR	Approx 28 day cost at this dose
Morphine modified-release (Zomorph)	2.5	20mg bd	50mg bd	£6.94* (£3.47 for 10mg 60-cap pack)
Oxycodone modified-release (Longtec)	5	10mg bd	50mg bd	£17.50*
Oxycodone with Naloxone (Targinact)	5	10mg bd	50mg bd	£42.32*
Tramadol modified-release (Zydol SR)	0.25 – 0.4	200mg bd	50mg bd	£36.52*
Fentanyl patch	250 – 375	12 mics/hr	50mg bd	£25.18* (£12.59 for 5 patches)
Buprenorphine patch (BuTrans)	187.5 – 287.5	20mics/hr	50mg bd	£57.46*
Tapentadol			50mg bd	£24.91*

*(Prices from BNF July 2015)

The maximum licenced daily dose of Tapentadol SR is 500mg (250mg bd) – equivalent to Morphine 100mg bd. It is recommended that patients taking higher doses of strong opiates be reduced to this dose before conversion is attempted. (Patient titration/dosing chart available from pain dept) or online - www.eclipsesolutions.org.

The synergistic action of Tapentadol SR means that it provides equivalent analgesia to “pure” opiates with less opiate receptor occupancy. When switching to Tapentadol, patients may experience symptoms of opiate withdrawal – particularly at higher doses.

Strategy:

- 1 Warn the patient of possibility of withdrawal symptoms and if required supply an extra opiate to take as required for 3 days after the switch, such as oramorph 10mg 6hourly prn
- 2 Introduce Tapentadol gradually, in steps of 50mg bd, reducing the current opiate by an equivalent amount.

Example – Patient taking Zomorph/ MST 80mg bd. Tapentadol SR equivalent 200mg bd

Day 1-3: Take Zomorph/MST 60mg bd plus Tapentadol SR 50mg bd

Days 4-6 Take Zomorph/MST 40mg bd plus Tapentadol SR 100mg bd

Days 7-9 Take Zomorph/ MST 20mg bd plus Tapentadol SR 150mg bd

Thereafter: Take Tapentadol SR 200mg bd

Alt: See patient titration/dosing chart available from pain department.

The SPC is available at <http://www.medicines.org.uk>

Further information for prescribers and for patients is available from the manufacturer at:

www.palexia.co.uk

Standard precautions for use of strong opioids still apply.

Additional notes:

- **Always prescribe the long-acting preparation Tapentadol. (Tapentadol SR)**
- No dose adjustment is required for mild or moderate renal failure, or mild hepatic failure.
- Tapentadol should be avoided in patients on MAOI's or with severe renal or hepatic failure.
- Exercise caution in patients with reduced seizure threshold or moderate hepatic failure.

Alternative dose conversion chart:

Morphine 12hr dose (BD) MST/ Zomorph	Tapentadol 12hr dose (BD) Palexia SR	Tramadol 12 hour dose (BD)	Oxycodone 12hr dose (BD) Oxycontin SR	Fentanyl Transdermal Patch change every 72 hrs	Buprenorphine Transdermal Patch B=Butrans change 7 days T =Transtec change 4 days
	Palexia SR: Oxycodone CR- 5:1 Palexia SR: Morphine (Oral) – 2.5:1			If stopping or starting patches refer to Fentanyl SPC for guidance.	If stopping or starting patches refer to Buprenorphine SPC for guidance
					B 5mcg/hr
					B 10mcg/hr
					B 20mcg/hr
10			5		B 30mcg/hr
15	50	200	7.5	12	T 35mcg/hr
30	50		15	12	T 35mcg/hr
45	100		25	25	T 52.5mcg/hr
60	150		30	37	T 70mcg/hr
90	200		45	50	T 105mcg/hr
120	250		60	62	T 140mcg/hr

Original guideline prepared by Dr Keith Mitchell, Pain Consultant, RCHT. 28/4/2012

Reviewed and Updated by Dr Keith Mitchell, Pain Consultant, RCHT. 19/8/2015.

ⁱ Lange B et al. Efficacy and safety of tapentadol prolonged release for chronic osteoarthritis pain and low back pain. *Adv Ther.* 2010 Jun;27(6):381-99

ⁱⁱ Baron R et al. Effectiveness of Tapentadol Prolonged Release (PR) Compared with Oxycodone/Naloxone PR for the Management of Severe Chronic Low Back Pain with a Neuropathic Component: A Randomized, Controlled, Open-Label, Phase 3b/4 Study. *Pain Pract.* 2015 Jun

ⁱⁱⁱ Steigerwald I et al. Effectiveness and safety of tapentadol prolonged release for severe, chronic low back pain with or without a neuropathic pain component: results of an open-label, phase 3b study. *Curr Med Res Opin.* 2012 Jun;28(6):911-36