

## Working in partnership

### SHARED CARE PRESCRIBING GUIDELINE

#### TAPENTADOL (PALEXIA SR ®) in Adults

as a third line agent when other opiates have been ineffective / not tolerated

#### NOTES to the GP

The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing this drug.

The questions below will help you confirm this:

- Is the patient's condition predictable or stable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the consultant within 14 days, outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with the appropriate Milton Keynes Hospital specialist service, who will be willing to provide training and support.

It would not normally be expected that a GP would decline to share prescribing on the basis of cost.

**The patient's best interests are always paramount**

**Date prepared:** July 2016 (Updated August 2018; November 2020)

**Review date:** November 2022

**Approved by (date approved):** Milton Keynes Prescribing Advisory Group (November 2020)

#### Introduction and reason for shared care

This shared care guideline has been prepared to support the transfer of responsibility for prescribing Tapentadol (Palexia SR ®) from secondary to primary care. This guideline does not cover the use of the immediate release formulation of tapentadol.

Tapentadol sustained release is a schedule 2 controlled drug. It is a centrally acting oral opioid analgesic combining two mechanisms of action: Mu-opioid receptor agonism and noradrenaline reuptake inhibition (MOR-NRI). It is licensed for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.

Tapentadol sustained release tablets (Palexia SR®) has been given an amber categorisation within the "traffic light" system as a third line opiate option where morphine has not been effective or tolerated. Use of the drug is expected to be in accordance with the Faculty of Medicine Good Practice Guidance 'Opioids Aware: A resource for patients and healthcare professionals to support prescribing of opioid medicines for pain'.

This guideline applies to patients who have been initiated and prescribed tapentadol sustained release tablets (Palexia SR®) for 28 days by a Consultant in Chronic Pain and in whom response to treatment has been assessed.

**NB. This guideline should be read in conjunction with the 'Guidelines for Pharmacological Management of Chronic Pain in Adults across the Milton Keynes Health Economy'.**

## TAPENTADOL (PALEXIA SR ®)

### 1. CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE

#### Shared Care

This shared care guideline outlines ways in which the responsibilities for managing the prescribing of tapentadol can be shared between the Consultant and General Practitioner (GP). If the GP does not feel confident to take on these responsibilities, then he or she is under no obligation to do so. In such an event the GP should discuss their concerns with the Consultant making the request to initiate shared care; where agreement to transfer care in a safe manner cannot be agreed the decision on continuing / changing treatment remains with the consultant. If a consultant asks the GP to prescribe this drug, the GP should respond this request as soon as practicable. Sharing of care assumes communication between the Consultant, GP and patient. The intention to share care is usually explained to the patient by the Consultant initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

Shared Care is only appropriate if it provides the optimum solution for the patient. Patients will only be referred to the GP once the GP has agreed in each individual case.

The doctor or non-medical prescriber who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

#### Licensed Indication for Therapy

Tapentadol Prolonged Release Tablets (Palexia SR®) are indicated for the management of severe chronic pain in adults which can be adequately managed only with opioid analgesics.

#### Preparations Available

Tapentadol Prolonged Release Tablets 50mg  
 Tapentadol Prolonged Release Tablets 100mg  
 Tapentadol Prolonged Release Tablets 150mg  
 Tapentadol Prolonged Release Tablets 200mg  
 Tapentadol Prolonged Release Tablets 250mg

### 2. AREAS OF RESPONSIBILITY

#### Hospital Consultant Responsibilities

1. To assess the suitability of the patient for treatment with tapentadol sustained release, in view of their previous medication history (including review of use of serotonergic medications which may increase the risk of serotonin syndrome), ensuring it is in line with the local guideline.
2. To determine a management strategy and where appropriate
  - to initiate and stabilise the patient on treatment, prescribing the first 28 days treatment;
  - to assess response to first months treatment;
  - to obtain agreement from the patient's GP to continue prescribing once treatment has been stabilised;
  - to monitor the patient and their therapy every six months (for patients on long term treatment);
  - to ensure therapy is discontinued where applicable.
3. To explain the possible side effects of the medication to the patient and emphasise the importance of regular monitoring.
4. To explain to the patient about DVLA restrictions on driving.
5. To ensure that patients know what to do and who to contact if they experience adverse events or an exacerbation of their condition.
6. To provide the GP with appropriate prescribing information and any additional information requested, and to offer telephone support.
7. To agree with the GP arrangements for any ongoing monitoring of the patient's condition to ensure the safe use of tapentadol.
8. To be available for advice if the patient's condition changes and to arrange follow up in clinic at intervals to monitor the progress of the disease and review the continued use of tapentadol.
9. To ensure that procedures are in place for the re-referral of the patient by the GP or provision of advice to the GP.
10. To ensure the patient has given informed consent to their treatment.
11. To liaise with the GP on any suggested changes in prescribed therapy / notify GP of any changes in the

patient's condition as assessed on follow up.  
 12.To inform the GP when it is considered appropriate to discontinue treatment.  
 13.To report any adverse events. Reporting forms can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

**General Practitioner Responsibilities**

1. Initially, to refer the patient to the specialist for pain management and advice on treatment.
2. To prescribe tapentadol sustained release at the agreed dose after the initial 28 day period and monitor the patient's ongoing response to tapentadol sustained release.
3. To carry out any agreed monitoring reporting the results to the specialist if appropriate.
4. To deal with general health issues of the patient.
5. To liaise with the consultant regarding any complications of treatment.
6. To consider any side-effects reported by the patient and to discuss with the consultant if necessary.
7. To avoid or appropriately manage the drug interactions as listed below and in the current BNF.
8. To ensure ongoing reviews of the patient's condition.
9. To monitor patients for any signs of drug misuse or addiction.
- 10.To ensure that therapy is discontinued where applicable.
- 11.To report any adverse events. Reporting forms can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).
- 12.To refer back to the hospital consultant when there is a) no response to treatment; b) unexpected dose escalation; c) development of new symptoms.

**Patient Responsibilities**

1. To report to the Consultant or GP if he / she does not have a clear understanding of the treatment.
2. To ensure the medication is stored safely and securely and taken according to the prescription.
2. To attend planned Consultant and GP appointments.
3. To share any concerns in relation to treatment with tapentadol with their GP or Consultant.
4. To adhere to any advice given regarding driving or operating machinery.
5. To report any effects on driving to the DVLA.
6. To report pregnancy or suspected pregnancy during treatment with tapentadol.
7. To avoid alcohol during treatment with tapentadol.
8. To seek help urgently if suspected side effects appear or the patient is otherwise unwell.
9. To agree to treatment being discontinued if the desired effect is not achieved.

**3. COMMUNICATION AND SUPPORT**

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| <p><b>Hospital contacts:</b><br/>                 (the referral letter will indicate named consultant)</p> <p><b>Milton Keynes University Hospital NHS Foundation Trust</b><br/> <b>Hospital Campus</b><br/> <b>Standing Way</b><br/> <b>Eaglestone</b><br/> <b>Milton Keynes</b><br/> <b>MK6 5LD</b></p> <p>Tel: 01908 660033 x 87007<br/>                 Fax: n/a<br/>                 E-mail: <a href="mailto:pain.clinic@mkuh.nhs.uk">pain.clinic@mkuh.nhs.uk</a></p> | <p><b>Out of hours contacts &amp; procedures:</b></p> <p>Chronic Pain Team 01908 997050<br/> <a href="mailto:SchedulingCentralBooking@mkuh.nhs.uk">SchedulingCentralBooking@mkuh.nhs.uk</a><br/>                 Dr Yaser Mehrez (Secretary) 01908 986662<br/> <a href="mailto:yaser.mehrez@mkuh.nhs.uk">yaser.mehrez@mkuh.nhs.uk</a><br/>                 Dr Sarah Aturia (Secretary) 01908 986662<br/> <a href="mailto:sarah.aturia@mkuh.nhs.uk">sarah.aturia@mkuh.nhs.uk</a><br/>                 Medicines Information 01908 995738<br/> <a href="mailto:medicines.information@mkuh.nhs.uk">medicines.information@mkuh.nhs.uk</a></p> |
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**Specialist support/resources available to GP including patient information:**

[www.formularymk.nhs.uk](http://www.formularymk.nhs.uk)  
 'Guidelines for Pharmacological Management of Chronic Pain in Adults across the Milton Keynes Health Economy'.

#### 4. CLINICAL INFORMATION

|                          |   |
|--------------------------|---|
| <b>Indication(s):</b>    | <p>Tapentadol sustained release is a schedule 2 controlled drug. It is a centrally acting oral opioid analgesic combining two mechanisms of action: Mu-opioid receptor agonism and noradrenaline reuptake inhibition (MOR-NRI). It is licensed for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.</p> <p>Tapentadol is an opioid agonist and a controlled substance that can be abused in a manner similar to other opioid agonists. Routine monitoring for signs of misuse, abuse and addiction is recommended, as these drugs carry a risk of addiction even under appropriate medical use.</p> <p>Cases of life threatening serotonin syndrome have been reported with the concurrent use of tapentadol and serotonergic drugs. Serotonin syndrome may include mental status changes (e.g. agitation, hallucinations), autonomic instability (e.g. tachycardia, labile blood pressure, and hyperthermia) neuromuscular changes (e.g. hyperreflexia, incoordination) and or gastrointestinal symptoms.</p> <p>Serotonergic drugs comprise Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin and Noradrenaline Reuptake Inhibitors (SNRIs), Tricyclic antidepressants (TCAs), Triptans and drugs which impair the metabolism of serotonin including MAOIs. If concomitant treatment with SSRIs, SNRIs, TCAs, Triptans or MAOIs is clinically indicated careful observation of the patient is advised.</p>  |
| <b>Place in Therapy:</b> | <p><b>Tapentadol Prolonged Release Tablets</b> should only be prescribed by a GP following initiation and assessment of benefit by a Consultant in Chronic Pain for selected patients who have not responded to treatments with morphine and other adjunctive therapies and after careful review by the consultant.</p> <p>Subject to individual patient need the following approach is recommended:-</p> <p><b>Step 1: Non-Opioid Analgesics +/- Non Steroidal Anti-inflammatory</b><br/><i>Paracetamol + / - Ibuprofen or Naproxen</i></p> <p><b>Step 2a Weak Opioid</b><br/><i>Codeine Phosphate</i></p> <p><i>If ineffective or not tolerated <u>then</u></i></p> <p><b>Step 2b: Moderate to Strong Opioid</b><br/><i>Tramadol (Low Dose) increased to Tramadol (High Dose)</i></p> <p><b>Step 3a: Strong Opioids</b><br/><i>(i) Oral Morphine MR (Low Dose) or (ii) Buprenorphine Patch (if morphine not tolerated)</i></p> <p><i>If ineffective or not tolerated <u>then</u></i></p> <p><b>Step 3b: Strong Opioids (High Dose)</b><br/><i>(i) Oral Morphine MR (High Dose) or (ii) Oxycodone MR or (iii) Fentanyl Patch (if morphine not tolerated)</i></p> <p><i>If ineffective or not tolerated <u>then the option for management as determined by the Consultant may be</u></i></p> <p><b>Step 3c: Oral Tapentadol Modified Release</b></p> <p><b>(For further details see Guideline for the Pharmacological Management of Chronic Pain across the Milton Keynes Health Economy – accessible via <a href="http://www.formularymk.nhs.uk">www.formularymk.nhs.uk</a>)</b></p> |

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| <b>Therapeutic summary:</b>                  | Tapentadol sustained release is a schedule 2 controlled drug. It is a centrally acting oral opioid analgesic combining two mechanisms of action: Mu-opioid receptor agonism and noradrenaline reuptake inhibition (MOR-NRI). It is licensed for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.   |
| <b>Dose &amp; route of administration:</b>   | <ul style="list-style-type: none"> <li>• Tapentadol prolonged release tablets (Palexia SR®) are available in 50mg, 100mg, 150mg, 200mg and 250mg strengths.</li> <li>• The initial dose should take into account previous opioid type and dose (see Table 1, page 10).</li> <li>• Titration should be in increments of 50mg twice daily every three days to achieve adequate pain control whilst minimising undesirable events.</li> <li>• Total daily doses greater than 500mg have not yet been studied and are not recommended.</li> <li>• There is no dose adjustment recommended in patients with mild or moderate renal impairment.</li> <li>• There is no dose adjustment recommended in patients with mild hepatic impairment.</li> <li>• When switching from other opioids to Tapentadol some withdrawal symptoms eg. agitation, muscle aches and sweating may occur.</li> </ul> |
| <b>Duration of treatment:</b>                | Titrated and ongoing according to response  |
| <b>Preparations available (Manufacturer)</b> | <b>Palexia SR (Grunenthal)</b><br>Tapentadol Prolonged Release Tablets 50mg<br>Tapentadol Prolonged Release Tablets 100mg<br>Tapentadol Prolonged Release Tablets 150mg<br>Tapentadol Prolonged Release Tablets 200mg<br>Tapentadol Prolonged Release Tablets 250mg   |

**Summary of Adverse Effects:**

- The consultant must be notified immediately about any serious adverse effect.
- The adverse drug reactions that were experienced by patients in the placebo controlled trials performed with Tapentadol sustained release were predominantly of mild and moderate severity.
- The most frequent adverse drug reactions were in the gastrointestinal and central nervous system (nausea, dizziness, constipation, headache and somnolence).

The table below lists adverse drug reactions that were identified from clinical trials performed with Tapentadol sustained release. They are listed by class and frequency.

| ADVERSE DRUG REACTIONS           |                      |  |   |                                    |
|----------------------------------|----------------------|--|---|------------------------------------|
| System Organ Class               | Frequency            |  |   |                                    |
|                                  | Very Common (≥1/10); | Common (≥1/100, <1/10);  | Uncommon (≥1/1,000, <1/100)   | Rare (≥1/10,000, <1/1,000);        |
| Immune system disorders          |                      |  | Drug hypersensitivity   |                                    |
| Metabolism & nutrition disorders |                      | Decreased appetite   | Weight decreased  |                                    |
| Psychiatric disorders            |                      | Anxiety, depressed mood, sleep disorder, nervousness, restlessness | Disorientation, confusional state, agitation, perception disturbances, abnormal dreams, euphoric mood | Drug dependence, thinking abnormal |

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| Nervous system disorders                      | Dizziness, somnolence, headache | Disturbance in attendance, tremor, muscle contractions involuntary             | Depressed level of consciousness, memory impairment, syncope sedation, balance disorder, dysarthria, hypoesthesia, paresthesia | Convulsion, presyncope, coordination abnormal |
| Eye disorders                                 |                                 |  | Visual disturbance   |   |
| Cardiac disorders                             |                                 |  | Heart rate increased, heart rate decreased   |   |
| Vascular disorders                            |                                 | Flushing   | Blood pressure decreased   |   |
| Respiratory, thoracic & mediastinal disorders |                                 | Dyspnoea   |  | Respiratory depression                        |
| Gastrointestinal disorders                    | Nausea, constipation            | Vomiting, diarrhoea, dyspepsia   | Abnormal discomfort  | Impaired gastric emptying                     |
| Skin & subcutaneous tissue disorders          |                                 | Pruritus, hyperhidrosis, rash  | Urticaria  |   |
| Renal and urinary disorders                   |                                 |  | Urinary hesitation, pollakiuria  |   |
| Reproductive system & breast disorders        |                                 |  | Sexual dysfunction   |   |
| General disorders & administration            |                                 | Asthenia, fatigue, feeling of body temperature change, mucosal dryness, oedema | Drug withdrawal syndrome, feeling abnormal, irritability   | Feeling drunk, feeling of relaxation          |

Clinical trials performed with Tapentadol sustained release with patient exposure up to 1 year have shown little evidence of withdrawal symptoms eg. agitation, muscle aches and sweating upon abrupt discontinuations and these were generally classified as mild, when they occurred. Nevertheless, physicians should be vigilant for symptoms of withdrawal and treat patients accordingly should they occur.

### Effects on Ability to Drive and Use Machines

Tapentadol sustained release may have major influence on the ability to drive and use machines due to the fact that it may adversely affect central nervous system functions. This has to be expected especially at the beginning of treatment, at any change of dosage as well as in connection with alcohol or tranquilisers. Patients should be cautioned as to whether driving or use of machines is permitted.

#### Monitoring Requirements by specialist:

- Adequacy of analgesia when a repeat prescription is issued (2<sup>o</sup> care for the first month of treatment and 1<sup>o</sup> care beyond this)
- Side effects
- Renal function – only if any pre-existing renal dysfunction.

#### Monitoring Requirements by GP:

- Adequacy of analgesia when a repeat prescription is issued (2<sup>o</sup> care for the first month of treatment and 1<sup>o</sup> care beyond this)
- Side effects
- Renal function – only if any pre-existing renal dysfunction
- Referral back to secondary care specialist if patient has any analgesic failure, unable to tolerate therapy, develops severe renal impairment or hepatic impairment.

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| <p><b>Clinically Relevant Drug Interactions:</b></p>                 | <p><b>See BNF or SPC for further information</b></p> <ul style="list-style-type: none"> <li>• Treatment with Tapentadol sustained release should be avoided in patients who are receiving monoamine oxidase (MAO) inhibitors or who have taken them within the last 14 days due to potential additive effects on synaptic noradrenaline concentrations which may result in adverse cardiovascular events, such as hypertensive crisis.</li> <li>• Medicinal products like benzodiazepines, barbiturates and opioids may enhance the risk of respiratory depression if taken in combination with tapentadol sustained release. Central nervous system (CNS) depressants (e.g. benzodiazepines, antipsychotics, H1-antihistamines, opioids, alcohol) can enhance the sedative effect of tapentadol and impair vigilance. Therefore, when a combined therapy of tapentadol sustained release with a respiratory or CNS depressant is contemplated, the reduction of dose of one or both agents should be considered.</li> <li>• For patients on tapentadol treatment, caution should be exercised if concomitant drug administration of strong enzyme inducing drugs (e.g. rifampicin, phenobarbital, St John's Wort (hypericum perforatum)) starts or stops, since this may lead to decreased efficacy or risk for adverse effects, respectively.</li> </ul>  |
| <p><b>Clinically Relevant Precautions and Contraindications:</b></p> | <p><b>See BNF or SPC for further information</b></p> <p>Tapentadol is contraindicated in:</p> <ul style="list-style-type: none"> <li>• Patients with hypersensitivity to tapentadol or to any of the excipients (see SPC for details of excipients)</li> <li>• Situations where active substances with mu-opioid receptor agonist activity are contraindicated, i.e. patients with significant respiratory depression (in unmonitored settings or the absence of resuscitative equipment), and patients with acute or severe bronchial asthma or hypercapnia.</li> <li>• Patients who has or is suspected of having paralytic ileus.</li> <li>• Patients with acute intoxication with alcohol, hypnotics, centrally acting analgesics, or psychotropic active substances.</li> </ul> <p>Tapentadol is not recommended in:</p> <ul style="list-style-type: none"> <li>• Patients with severe hepatic impairment due to lack of trial data.</li> <li>• Patients with severe renal impairment due to lack trial data.</li> <li>• Children or adolescents below 18 years of age.</li> </ul> <p><b>Pregnancy and Lactation</b></p> <p>There is very limited amount of data from the use in pregnant women. Studies in animals have not shown teratogenic effects. However, delayed development and embryotoxicity were observed at doses resulting in exaggerated pharmacology. Tapentadol sustained release should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.</p> <p><b>Labour and Delivery</b></p> <p>The effect of tapentadol on labour and delivery in humans is unknown. Tapentadol sustained release is not recommended for use in women during and immediately before labour and delivery. Due to the mu-opioid receptor agonist activity of tapentadol, new-born infants whose mothers have been taking tapentadol should be monitored for respiratory depression.</p> |

|                                 |   |
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|                                 | <p><b>Lactation</b></p> <p>There is no information on the excretion of tapentadol in human milk. From a study in rat pups suckled by dams dosed with tapentadol, it was concluded that tapentadol is excreted via milk. Therefore, a risk to the suckling child cannot be excluded. Tapentadol sustained release should not be used during breast feeding.</p> <p><b>Note: This guideline was prepared using information available at the time of preparation, but users should always refer to the manufacturer's current edition of the Summary of Product Characteristics (<a href="http://www.emc.medicines.org.uk">http://www.emc.medicines.org.uk</a>) for more details.</b></p>  |
| <p><b>Practical issues:</b></p> | <p><b>Additional Information / Special Warnings</b></p> <ul style="list-style-type: none"> <li>• Tapentadol prolonged release has a potential for abuse and addiction. This should be considered when prescribing or dispensing Tapentadol PR (Palexia SR ®) in situations where there is concern about an increased risk of misuse, abuse, addiction or diversion. All patients treated with active substances that have mu-opioid receptor agonist activity should be carefully monitored for signs of abuse and addiction.</li> <li>• Tapentadol sustained release should be used with caution in patients with moderate hepatic impairment; treatment should be initiated at the lowest available dose strength, i.e. 50 mg tapentadol sustained release tablet, and not be administered more frequently than once every 24 hours. At initiation of therapy a daily dose greater than 50 mg tapentadol sustained release tablet is not recommended.</li> <li>• A dose adaptation in elderly patients is not required. However, as elderly patients are more likely to have decreased renal and hepatic function, care should be taken in dose selection.</li> <li>• Tapentadol should not be used in patients who may be particularly susceptible to the intracranial effects of carbon dioxide retention.</li> <li>• Tapentadol should be used with caution in patients with biliary tract disease.</li> <li>• At high doses or in mu-opioid receptor agonist sensitive patients, Tapentadol sustained release may produce dose-related respiratory depression. Therefore, should be administered with caution to patients with impaired respiratory functions and should be employed only under careful medical supervision at the lowest effective dose in such patients. If respiratory depression occurs, it should be treated as any mu-opioid receptor agonist-induced respiratory depression.</li> </ul> <p><b>MHRA Drug Safety Update: Advice for Healthcare Professionals Issued 9<sup>th</sup> January 2019</b></p> <ul style="list-style-type: none"> <li>• As for all opioid medicines, tapentadol can induce seizures.</li> <li>• Tapentadol should be prescribed with care in patients with a history of seizure disorders or epilepsy.</li> <li>• Tapentadol may increase seizure risk in patients taking other medicines that lower seizure threshold, for example, antidepressants such as serotonin reuptake inhibitors (SSRIs), serotonin-noradrenaline reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs) and antipsychotics.</li> <li>• Serotonin Syndrome has been reported when Tapentadol is used in combination with serotonergic antidepressants.</li> <li>• Withdrawal of the serotonergic medicine, together with supportive symptomatic care, usually brings about a rapid improvement in serotonin syndrome.</li> </ul> |



**Supply** (Costs as per BNF November 2020)

| Preparation                 | Pack Size | Cost    |
|-----------------------------|-----------|---------|
| Tapentadol PR Tablets 50mg  | 28        | £12.46  |
| Tapentadol PR Tablets 50mg  | 56        | £24.91  |
| Tapentadol PR Tablets 100mg | 56        | £49.82  |
| Tapentadol PR Tablets 150mg | 56        | £74.73  |
| Tapentadol PR Tablets 200mg | 56        | £99.64  |
| Tapentadol PR Tablets 250mg | 56        | £124.55 |

Annual Treatment Cost: £323.83 to £1619.15 (assuming dose range of 50mg BD to 250mg BD).

**Key references:**
**References**

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2. Summary of Product Characteristics for Palexia SR® (Tapentadol).  
<http://www.medicines.org.uk/emc/medicine/28373>  
[Accessed 11/11/2020]
3. MHRA Drug Safety Alert January 2019: Tapentadol (Palexia): risk of seizures and reports of serotonin syndrome when co-administered with other medicines  
<https://www.gov.uk/drug-safety-update/tapentadol-palexia-risk-of-seizures-and-reports-of-serotonin-syndrome-when-co-administered-with-other-medicines>  
[Accessed 11/11/2020]

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## Table 1: Opiate Dose Conversion Chart

Use the conversion chart below to work out the equivalent doses of different opiate drugs. The formula to work out the dose is under each drug name. This is to be used as a guide rather than a set of definite equivalences. Some doses have been rounded up or down to fit with the preparations available. Oral morphine SR should always be the first line treatment for the management of severe chronic pain in adults requiring treatment with an opioid analgesic (Step III of WHO ladder). Tapentadol should only be considered as a second-line option for those unable to tolerate morphine SR or where morphine SR has failed to provide adequate pain control

| Oral Opiate (mg)                           |                             |   |  |   |  | Opiate by Patch  |
|--|-----------------------------|---|--|---|--|--|
| Morphine 12 hour dose (BD)<br>MST/ Zomorph | Morphine 24 hour total dose | Tapentadol 12 hour dose (BD)<br>Palexia SR                          | Tapentadol 24 hour total dose                            | Oxycodone 12 hour dose (BD)<br>Oxycontin SR | Oxycodone 24 hour total dose                         | Fentanyl Transdermal Patch<br>Change every 72 hrs                  |
|  |                             | Palexia SR, Oxycodone CR 5:1<br><br>Palexia SR, Oral Morphine 2.5:1 | Calculated by multiplying 24hr oral morphine dose by 2.5 |   | Calculated by dividing 24hrs oral morphine dose by 2 | If stopping or starting patches refer to Fentanyl SPC for guidance |
|  | 5                           |   |  |   |  |  |
|  | 10                          |   |  |   |  |  |
|  | 15                          |   |  |   |  |  |
| 10   | 20                          |   |  | 5   | 10   |  |
| 15   | 30                          | 50  | 100  | 7.5   | 15   | 12   |
| 30   | 60                          | 50  | 100  | 15  | 30   | 12   |
| 45   | 90                          | 100   | 200  | 25  | 50   | 25   |
| 60   | 120                         | 150   | 300  | 30  | 60   | 37   |
| 90   | 180                         | 200   | 400  | 45  | 90   | 50   |
| 120  | 240                         | 250   | 500  | 60  | 120  | 62   |

When switching between opioids, the nature of the previous medicinal product, administration and the mean daily dose should be taken into consideration. The patient should be counselled on the likelihood of it being a more difficult period whilst they change between drugs. They may experience an increase in pain before it becomes controlled again and they may require dose adjustments more or less frequently than expected.

After initiation of therapy the dose should be titrated individually to a level that provides adequate analgesia and minimises undesirable effects.

**TAPENTADOL (PALEXIA SR®) in Adults**  
**as a third line agent when other opiates have been ineffective / not tolerated**  
**Shared Care Guideline: Prescribing Agreement**  
**(Note: Sections A and B MUST be forwarded to GP and returned by GP back to the hospital together)**

| <b>Section A: To be completed by the hospital consultant initiating the treatment</b>   |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |
|---|--------|---|--------|------|--------|------|--------|--|--|--|--|--|--|--|--|
| <b>GP Practice Details:</b><br>Name: .....<br>Address: .....<br>Tel no: .....<br>Fax no: .....<br>NHS.net e-mail: .....   |        | <b>Patient Details:</b><br>Name: .....<br>Address: .....<br>DOB: ...../...../.....<br>Hospital number: .....<br>NHS number (10 digits): ..... |        |      |        |      |        |  |  |  |  |  |  |  |  |
| <b>Consultant name:</b> .....<br><b>Clinic name:</b> .....<br><b>Contact details:</b><br>Address: .....<br>Tel no: ..... Fax no: .....<br>NHS.net e-mail: .....   |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |
| <b>Diagnosis:</b> .....   |        | <b>Drug name &amp; dose to be prescribed by GP:</b> .....   |        |      |        |      |        |  |  |  |  |  |  |  |  |
| <b>Next hospital appointment:</b> ...../...../.....   |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |
| Dear Dr. ....,<br>Your patient was seen on ...../...../..... and I have started .....(insert drug name and dose) for the above diagnosis. I am requesting your agreement to sharing the care of this patient from ...../...../..... in accordance with the (attached) Shared Care Prescribing Guideline (approval date: ...../...../.....). Please take particular note of Section 2 where the areas of responsibilities for the consultant, GP and patient for this shared care arrangement are detailed. <p>Patient information has been given outlining potential aims and side effects of this treatment and .....* supplied (* insert any support materials issued such as patient held monitoring book etc where applicable). The patient has given me consent to treatment possibly under a shared care prescribing agreement (with your agreement) and has agreed to comply with instructions and follow up requirements.</p> <p>The following investigations have been performed on ...../...../..... and are acceptable for shared care. Please monitor.....every .....</p> |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |
| <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:25%;">Test</th> <th style="width:25%;">Result</th> <th style="width:25%;">Test</th> <th style="width:25%;">Result</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>   |        |   |        | Test | Result | Test | Result |  |  |  |  |  |  |  |  |
| Test  | Result | Test  | Result |      |        |      |        |  |  |  |  |  |  |  |  |
|   |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |
|   |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |
| Other relevant information: .....   |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |
| Consultant Signature: .....Date: .../.../.....  |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |
| <b>Section B: To be completed by the GP and returned to the hospital consultant as detailed in Section A above</b>  |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |
| Please sign and return your agreement to shared care within 14 days of receiving this request<br>Tick which applies:<br><input type="checkbox"/> I accept sharing care as per shared care prescribing guideline and above instructions<br><input type="checkbox"/> I would like further information. Please contact me on:.....<br><input type="checkbox"/> I am not willing to undertake shared care for this patient for the following reason:<br>.....<br>GP name: .....   |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |
| GP signature: .....Date: .../.../.....  |        |   |        |      |        |      |        |  |  |  |  |  |  |  |  |

**(Note: Sections A and B MUST be forwarded to GP and returned by GP back to the hospital together)**