TAPEXTADOL IMMEDIATE RELEASE (IR) TO TREAT MODERATE TO SEVERE ACUTE PAIN, AND TAPEXTADOL EXTENDED RELEASE (ER) TO TREAT SEVERE CHRONIC PAIN

<table>
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<tr>
<th>Name: generic (trade)</th>
<th>What it is</th>
<th>Indication</th>
<th>Date decision last revised</th>
<th>Decision status</th>
<th>NICE / SMC Guidance</th>
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<td>Tapentadol (Palexia®)</td>
<td>Opioid analgesic</td>
<td>IR - relief of moderate to severe acute pain. ER - management of severe chronic pain.</td>
<td>September 2014</td>
<td>Final</td>
<td>NICE – not on NICE work plan SMC – ER restricted recommendation for use. IR – not recommended for use.</td>
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IR tapentadol is **NOT RECOMMENDED** for secondary care or primary care prescribing.

ER tapentadol is **RECOMMENDED FOR RESTRICTED USE** for severe chronic non-palliative pain. **ONLY** to be initiated by secondary care specialists in chronic pain management in adults in line with the treatment guidelines as follows:

- 3rd line option after morphine, oxycodone and/or fentanyl in patients with a neuropathic component of pain.

- Initiation by specialist in pain management only: **NO primary care prescribing in first 4 months of treatment**. Patients presenting to primary care requesting supplies of tapentadol within the first 4 months of treatment should be advised to contact the specialist’s secretary to arrange further supplies from specialist (contact details in patient information leaflet).

- Specialist in pain management responsibilities:
  
  **Initiation:**
  - to prescribe for first 3 months (supplied from hospital pharmacy).
  - supply information to patient (including patient information leaflet) and GP confirming prescribing, supply and monitoring arrangements (all to remain with the specialist/hospital for the first 3 months).
  - complete tapentadol notification pro-forma.

  **Review:**
  - assess patient within 3 months of starting treatment and complete 3 month follow up pro-forma.
  - Treatment only to continue if 20% improvement in pain scale score AND a score of 5-7 on the Patient Global Impression of Change form.
  - if ineffective change treatment back to the most effective/best tolerated previously used strong opioid.
  - if effective prescribe a further 1 month and transfer prescribing responsibility to GP with comprehensive ongoing management information (see below).
  - follow-up patients at 3 monthly intervals for the 1st year.
  - complete annual follow up pro-forma for audit purposes.

**Refer to Hertfordshire Chronic Non-palliative Pain in Adults Treatment Guidelines for further information on chronic pain management**

**Information to be included within letter from specialist to GP for each patient**

- Current tapentadol dose. Usually start tapentadol modified-release tablets at 50mg twice daily and titrated up to 150mg twice daily if effective and tolerated.
- Titration schedule and target dose to increase to before next appointment.
- Dose tapering information if medicine is being changed or discontinued.
- Advice on management of side-effects and supportive medication (laxatives and anti-emetics).
- Advice on the use of non-opioids, weak opioids and immediate release morphine for ‘breakthrough’ pain.
- Advice if intolerance including next treatment option (starting dose, titration schedule & target dose).
- Details of next scheduled appointment with specialist.
- Details of GP review schedule and any specific monitoring requirements.
- Contact details for pain clinic for further advice for GP.

This HMMC recommendation is based upon the evidence available at the time of publication. The recommendation will be reviewed upon request in the light of new evidence becoming available.
Background Information

- Tapentadol is an opioid analgesic combining two mechanisms of action: mu-opioid receptor agonism and noradrenaline reuptake inhibition.
- Has potential for abuse and addiction. Caution use if risk of misuse, abuse, addiction, or diversion.
- The most frequent adverse drug reactions are gastrointestinal and central nervous system (nausea, dizziness, constipation, headache and somnolence).
- Withdrawal symptoms could occur after abrupt discontinuation of treatment. When a patient no longer requires therapy with tapentadol, it is advisable to taper the dose gradually to prevent withdrawal symptoms.
- May have major influence on the ability to drive and use machines because it may adversely affect central nervous system functions. This is to be expected especially at the beginning of treatment, when any dose changes occur and in connection with the use of alcohol or tranquillisers.
- Interactions with other medicines:
  - Caution with mixed mu-opioid agonist/antagonists or partial mu-opioid agonists (eg buprenorphine)
  - Isolated cases of serotonin syndrome reports with serotonergic medicines.
  - Caution if concomitant drug administration of strong enzyme inducing drugs started or stopped.
  - Medicinal products like benzodiazepines, barbiturates and opioids (analgesics, antitussives or substitution treatments) may enhance the risk of respiratory depression if taken in combination with tapentadol. CNS depressants (e.g. benzodiazepines, antipsychotics, H1-antihistamines, opioids, alcohol) can enhance the sedative effect of tapentadol and impair vigilance.
- At high doses or in mu-opioid receptor agonist sensitive patients, tapentadol may produce dose-related respiratory depression.
- As this is a new, black triangle▼ medication, all suspected adverse drug reactions should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the yellow card scheme: https://yellowcard.mhra.gov.uk/

Refer to Summary of Product Characteristics for full prescribing information http://www.medicines.org.uk/emc/

References

- Hertfordshire Chronic Non-palliative Pain in Adults Treatment Guidelines September 2014
- Tapentadol prolonged release tablets, Scottish Medicines Consortium, 13 June 2011 https://www.scottishmedicines.org.uk/SMC_Advice/Advice/654_10_tapentadol_SR_Palexia/tapentadol_SR_Palexia
- Bulletin 148, immediate release tapentadol for moderate to severe acute pain, Bedfordshire and Luton PCTs JPC, April 2011
- Bulletin 149, extended release tapentadol for severe chronic pain, Bedfordshire and Luton PCTs JPC, April 2011
- Tapentadol prolonged release for severe chronic pain, National Horizon Scanning Centre, University of Birmingham, December 2009.