

## Pharmacotherapeutic report, summary

Tapentadol (Palexia Retard®) for the indication 'severe chronic pain'

Recommendation by CVZ dated 28-10-2013, based on Evaluation by the WAR (Scientific Advisory Committee)

### Medicine (slow-release tablets for oral use)

**Registered indication.** "Palexia Retard® is indicated for the treatment of severe chronic pain in adults, which can only be adequately managed with opioid analgesics."

**Posology.** 50-250 mg twice daily, depending on individual response. Maximum daily dose 500 mg.

**Mechanism of action.** Tapentadol is a powerful analgesic with mu-opioid receptor agonistic and norepinephrine reuptake inhibitor properties. Tapentadol produces its analgesic effects without any pharmacologically active metabolite.

**Specific details.** Tapentadol was registered via a decentralised process. Tapentadol falls under the Opium Law in the Netherlands.

### Summary of the therapeutic value

**Intended effects.** 15 weeks of treatment of patients with severe chronic pain due to osteoarthritis of the knee, low back pain and diabetic neuropathy using individually titrated doses of tapentadol reduced pain scores to a similar extent as with oxycodone controlled-release tablets. Limitations include the placebo-controlled set-up instead of a direct comparison with morphine or oxycodone and the fact that 33-35% of the patients studied discontinued participation in the research.

**Unintended effects.** The side effects of tapentadol are comparable with those of the class of opioids. Insufficient substantiation exists for a clinically relevant difference in incidence of side effects of tapentadol in comparison with morphine and oxycodone.

**Experience.** Sufficient experience has been gained with tapentadol and oxycodone, and ample experience with morphine.

**Applicability.** The applicability of tapentadol has the same limitations as morphine, oxycodone and similar products due to the contraindications and extensive warnings/precautions.

**Ease of use.** Tapentadol, oxycodone and morphine are administered orally. Morphine is available in other forms as well as tablets.

#### **Final conclusion regarding therapeutic value.**

The therapeutic value of tapentadol for the treatment of severe chronic pain in adults who can only be treated with opioid analgesics is equivalent to that of morphine and oxycodone.

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*The original text of this excerpt from a **WAR-Report** of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the*

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