

equilibrium

balancing the burden
of chronic pain



Dear {insert customer name},

Thank you for taking the time to watch the Equilibrium webinar covering the management of chronic pain in primary care and behavioural change as well as completing the questionnaire.

Please find below your certificate of completion to add to your learning records.

If you haven't reviewed Grünenthal's chronic pain learning module, you can do this by clicking [this link](#), after which you will receive a certificate of completion.

Kind Regards,

{insert KAM details here and photo}



Pain Management

{insert customer name}

completed a multi-topic online webinar covering both
chronic pain management in primary care and
behavioural change with telemedicine produced by
Grünenthal with the following key learnings:



- ✓ Chronic Pain: an approach to management
- ✓ Treatment & management aims in primary care
- ✓ Medication reviews
- ✓ When to refer?
- ✓ Behavioural change through telemedicine



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PALEXIA® SR (tapentadol hydrochloride) Prolonged Release Tablets Prescribing Information

Refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** 50 mg (white), 100 mg (pale yellow), 150 mg (pale pink), 200 mg (pale orange) and 250 mg (brownish red) prolonged-release tablets contain 50 mg, 100 mg, 150 mg, 200 mg and 250 mg of tapentadol (as hydrochloride) respectively. **Indication:** Palexia SR is indicated for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics. **Dosage and method of administration:** Individualise according to severity of pain, the previous treatment experience and the ability to monitor the patient. Swallowed whole with sufficient liquid, not divided or chewed, with or without food. The tablet shell may not be completely digested and eliminated / seen in the patient's stool which has no clinical significance as the active substance will have already been absorbed. Initial dose 50 mg twice a day. Switching from other opioids may require higher initial doses. Titrate in increments of 50 mg twice a day every 3 days for adequate pain control. Total daily doses greater than 500 mg not recommended. **Discontinuation of treatment:** Taper dose gradually to prevent withdrawal symptoms. **Renal/hepatic impairment:** Not recommended in severe patients. Moderate hepatic impairment, exercise caution, at initiation do not exceed 50mg SR once daily. **Elderly:** May need dose adjustments. **Children below 18 years:** Not recommended. **Contraindications:** Hypersensitivity to ingredients, suspected or having paralytic ileus, acute intoxication with alcohol, hypnotics, centrally acting analgesics or psychotropics. Not for use when mu-opioid receptor agonists are contraindicated (e.g. significant respiratory depression, acute or severe bronchial asthma or hypercapnia). **Special warnings and precautions:** Abuse and addiction potential of Palexia SR should be considered where there is increased risk of misuse, abuse, addiction or diversion. All patients should be carefully monitored for signs of abuse and addiction. Concomitant use with sedating medicinal products such as benzodiazepines or related substances may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedating medicinal products should be reserved for patients for whom alternative treatment options are not possible. If used concomitantly, reduction of dose of one or both agents should be considered and the duration of the concomitant treatment should be as short as possible. The patients should be followed closely for signs and symptoms of respiratory depression and sedation. It is strongly recommended to inform patients and caregivers to be aware of these symptoms. At high doses or in mu-opioid receptor agonist sensitive patients, dose-related respiratory depression may occur. Caution and monitoring required with impaired respiratory function. Should not use in patients susceptible to intracranial effects of carbon dioxide retention (e.g. increased intracranial pressure, impaired consciousness or coma). Use with caution in head injury, brain tumors, moderate hepatic impairment and biliary tract disease including acute pancreatitis. Not recommended if history of or at risk of seizures. May increase the seizure risk in patients taking other medicinal products that lower the seizure threshold. Opioids can cause sleep-related breathing disorders including central sleep apnea (CSA) and sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. In patients who present with CSA, consider decreasing the total opioid dosage. Care should be taken when combining with mixed mu-opioid agonists/antagonists (e.g. pentazocine, nalbuphine) or partial mu-opioid agonists (e.g. buprenorphine). Should not use with hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. **Interactions:** The concomitant use with sedating medicinal products such as benzodiazepines or other respiratory or CNS depressants (other opioids, antitussives or substitution treatments, barbiturates, antipsychotics, H1-antihistamines, alcohol) increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. When combined therapy with a respiratory or CNS depressant is contemplated, the reduction of dose of one or both agents should be considered and the duration of the concomitant use should be limited. Can induce convulsions and increase the potential for selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, antipsychotics and other medicinal products that lower the seizure threshold to cause convulsions. There have been reports of serotonin syndrome in a temporal connection with the therapeutic use of tapentadol in combination with serotoninergic medicinal products such as SSRIs, SNRIs and tricyclic antidepressants. Use with strong inhibitors of uridine diphosphate transferase isoenzymes (involved in glucuronidation) may increase systemic exposure of Palexia SR. Caution if concomitant administration of strong enzyme inducing drugs (e.g. rifampicin, phenobarbital, St John's Wort) starts or stops as this may lead to decreased efficacy or risk for adverse events, respectively. Avoid use in patients who have taken monoamine oxidase inhibitors (MAOIs) within the last 14 days, due to cardiovascular events. **Pregnancy and Breast-feeding:** Use in pregnancy only if the potential benefit justifies the potential risk to the foetus. Long term maternal opioid use during pregnancy may cause neonatal withdrawal syndrome (NOWS). NOWS can be life threatening. Not recommended during and immediately before labour and delivery. Do not use during breast feeding. New-born infants whose mothers have been taking tapentadol should be monitored for respiratory depression. **Driving and using machines:** May have major effect on ability to drive and use machines, especially at the beginning or change in dosage, in connection with alcohol or tranquilisers. **Undesirable effects:** **Very common (≥1/10):** dizziness, somnolence, headache, nausea, constipation. **Common (≥1/100, <1/10):** decreased appetite, anxiety, depressed mood, sleep disorder, nervousness, restlessness, disturbance in attention, tremor, involuntary muscle contractions, flushing, dyspnoea, vomiting, diarrhoea, dyspepsia, pruritus, hyperhidrosis, rash, asthenia, fatigue, feeling of body temperature change, mucosal dryness, oedema. **Other important undesirable/ serious effects observed in clinical trials and/or post-marketing:** drug hypersensitivity, depressed level of consciousness, mental impairment, syncope (*uncommon* ≥1/1000, <1/100), angioedema, anaphylaxis and anaphylactic shock, respiratory depression, convulsion, impaired gastric emptying, drug dependence (*rare* ≥1/10,000, <1/1000), delirium (*unknown*). No evidence of increased risk of suicidal ideation or suicide with Palexia SR. Prescribers should consult the SmPC in relation to all adverse reactions. **Overdose:** Seek specialist treatment (see SmPC). **Legal classification:** POM, CD (Schedule II). **Marketing Authorisation numbers, pack sizes and basic NHS cost:** 50 mg: PL 50414/0014, 28 pack (£12.46) and 56 pack (£24.91); 100 mg: PL 50414/0015, 56 pack (£49.82); 150 mg: PL 50141/0016, 56 pack (£74.73); 200 mg: PL 50414/0017, 56 pack (£99.64) and 250 mg: PL 50414/0018, 56 pack (£124.55). **Marketing Authorisation Holder:** Grünenthal Pharma Ltd. 4045 Kingswood Road, Citywest Business Park, Citywest, Co.Dublin, Ireland.



Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Grünenthal Ltd (telephone 0870 351 8960).