**Table E11. Data abstraction of randomized controlled trials of antiseizure medications**

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| **Author, Year** | **Country Number of Centers and Setting** | **Inclusion Criteria** | **Number Randomized, Analyzed**  **Attrition** | **Intervention** | **Study Participants** | **Duration of Pain (acute, subacute, chronic)** |
| Baron, 2010 | USA, Canada,  and Europe  Multicenter | ≥18 years of age, pain consistent  with chronic lumbosacral radiculopathy due to spinal stenosis, leg pain greater than back pain, pain present ≥3 months, stable for ≥4 weeks, mean weekly pain score >4; placebo nonresponder and pregabalin responder (including  ≥30% improvement in pain) in run- in period  Exclude: Radicular pain for >4 years, surgery for lumbosacral radiculopathy in last 6 months, more than one previous spinal surgery for L5-S1 pain/radiculopathy, epidural injection in last 6 weeks | Randomized: 218 (111  vs. 107) of 378 in run- in period  Analyzed: 211 (110 vs.  108)  Attrition: 14% (31/218) | Placebo run-in period for  7 days, then pregabalin run-in for 28 days, then:  A: Pregabalin: Optimal dose from run-in period (mean 410 mg) x 5 w, then 1 w taper (n=110)  B: Placebo: Pregabalin taper x 1 w, then placebo x 4 w, then taper x 1 w (n=108) | Mean age: 52 vs. 53  years  Female: 49% vs.  55%  Race: Not reported  Baseline pain (mean,  0-10 VAS): 6.36 vs.  6.39  Baseline function: Not reported | Chronic (≥3  months); mean duration not reported |

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| **Author, Year** | **Duration of**  **Followup** | **Results** | **Adverse Events Including**  **Withdrawals** | **Funding**  **Source** | **Quality**  **Rating** |
| Baron, 2010 | 5 weeks (at  end of therapy) | A vs. B  Pain (mean change from baseline, 0-10 VAS): -0.16 vs. 0.05 (p=0.33)  Pain ≥7/10 (days): 7.1% (8/108) vs. 6.4% (7/107) at 5 w  Loss of response (≥1 point increase in weekly mean pain score or use of rescue medication): 27.8% vs. 28.0% at 5 w, HR 0.87 (95% CI 0.52 to 1.47)  Medical Outcome Study Sleep Scale sleep disturbance (mean change, 0-100): 2.26 vs. 6.86 (p=0.03)  Medical Outcome Study Sleep Scale sleep quantity (mean change, hours): 0 vs. -0.43 (p=0.004)  No differences on other MOS Sleep Scale subscales  HADS anxiety (mean change, 0-21): -0.19 vs. 0.82 at 5 w (p=0.01) HADS depression (mean change, 0-21): -0.57 vs. 0.56 at 5 w (p=0.0006)  EQ-5D, RDQ: No differences, data not reported | A vs. B  Any adverse event: 40.9% (45/110) vs.  42.1% (45/107)  Serious adverse event: 1.8% (2/110)  vs. 0% (0/107)  Dizziness: 3.6% (4/110) vs. 1.9% (2/107)  Somnolence: 0.9% (1/110) vs. 0.9% (1/107)  Edema: 4.5% (5/110) vs. 1.9% (2/107) | Pfizer Inc. | Fair |

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| **Author, Year** | **Country Number of Centers and Setting** | **Inclusion Criteria** | **Number Randomized, Analyzed**  **Attrition** | **Intervention** | **Study Participants** | **Duration of Pain (acute, subacute, chronic)** |
| Baron, 2014 | Europe  Multicenter | ≥18 years of age, chronic (≥3  months) low back pain requiring a WHO step III analgesic (baseline pain thresholds specified for persons on step I or 2  analgesics), painDETECT score for neuropathic pain ≥13 (0 to 38 scale), tapentadol responder during run-in period  Exclude: Pregnant, breastfeeding, back pain due to cancer, painful procedure planned, other pain condition, comorbid conditions, alcohol or drug abuse, allergy or sensitivity to study drugs | Randomized: 313 (159  vs. 154) of 313 in run- in period  Analyzed: 309 (157 vs.  152)  Attrition: 17% (56/313) | Washout for 3-14 days,  then tapentadol PR run- in for 3 weeks, then:  A: Pregabalin + tapentadol PR: Pregabalin 150 mg/day x  1 w, 300 mg/day x 7 w + tapentadol PR 300 mg/day (n=157)  B: Tapentadol PR: Tapentadol 300 mg/day  + 100 mg/day x 1 w, tapentadol 300 mg/day +  200 mg/day x 7 w  (n=152) | Mean age: 56 vs. 58  years  Female: 54% vs.  62%  White: 99% vs. 100% Baseline pain: 5.9 vs.  5.9 (at randomization) Baseline function: Not reported | Chronic (≥ 3  months): mean 8.7 vs. 9.4 years |
| Kalita, 2014 | India  Single center | 15 to 65 years of age, low back  pain >3 months  Exclude: Chronic low back pain due to a specific cause, immunosuppressant therapy, anticancer drugs, post-transplant, post-spinal surgery, pregnant or breastfeeding, severe  neurological deficit due to radiculopathy or spinal stenosis | Randomized: 200 (97  vs, 193) Analyzed: 200  Attrition: 26% (53/200) | A: Pregabalin: 75 mg bid  x 2 w, 150 mg bid x 2 w,  300 mg bid, then increased if tolerated  and needed (mean dose  ~430 mg/day) (n=97)  B: Amitriptyline: 12.5  QHS x 2 w, 25 mg QHS x 4 w, then 50 mg QHS, then increased if tolerated and needed (mean dose 38 mg/day) (n=103) | Mean age: 42 vs. 42  years  Sex: Not reported Race: Not reported Baseline pain: 6.7 vs.  6.7  Baseline ODI: 42 vs.  42  Radiculopathy: 47% Spinal stenosis: 6% | Chronic (≥ 3  months): mean 36 vs.  35 years |

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| **Author, Year** | **Duration of**  **Followup** | **Results** | **Adverse Events Including**  **Withdrawals** | **Funding**  **Source** | **Quality**  **Rating** |
| Baron, 2014 | 9-10 weeks  (1-2 weeks after end of therapy) | A vs. B  Pain (mean change from baseline, 0-10 VAS): -1.6 vs. -1.7 at 9-10 w (p>0.05)  Leg pain (mean change from baseline, 0-10 VAS): -1.6 vs. -1.9 at  9-10 w  Patient satisfaction good, very good, or excellent: 73% (114/157)  vs. 67% (102/152) at 9-10 w  "Minimally", "much", or "very much" improved: 82% (129/157) vs.  81% (123/152) at 9-10 w  SF-12: No difference on any subscale at 9-10 w EQ-5D (mean, 0-10): 0.60 vs. 0.61 at 9-10 w HADS anxiety (mean): 5.8 vs. 6.0 at 9-10 w HADS depression (mean): 5.4 vs. 6.2 at 9-10 w | A vs. B  Any adverse events: 65% (103/159) vs.  64% (98/154)  Discontinued due to adverse events:  7.5% (12/158) vs. 7.8% (12/154) Dizziness: 17.6% vs. 11.0% Somnolence: 11.9% vs. 8.4% Nausea: 9.4% vs. 10.4% Headache: 8.2% vs. 6.5% Constipation: 5.0% vs. 7.1%  Dry mouth: 5.0% vs. 3.9% | Grunenthal  GmbH | Fair |
| Kalita, 2014 | 14 weeks  (at end of therapy) | A vs. B  Pain (mean, 0-10 VAS): 6.7 vs. 6.7 at baseline, 4.2 vs. 3.9 at 4 w,  3.8 vs. 2.8 at 16 w (estimated from graph; p>0.05 at all time points)  ODI (mean, 0-100): 42 vs. 42 at baseline, 30 vs. 26 at 4 w, 22 vs.  17 at 16 w (estimated from graph; p>0.05 at all time points)  Pain improved by >=50%: 39% (38/97) vs. 57% (59/103), RR 0.68 (95% CI 0.51 to 0.92)  ODI improved >20%: 50% (48/97) vs. 65% (67/103), RR 0.76 (955  CI 0.59 to 0.97)  Findings for dichotomous outcomes similar for patients with non- radicular back pain and radiculopathy; with or without neurological deficit | A vs. B  Any adverse event: 22% (29/97) vs.  17% (18/103)  Sedation: 4.1% (4/97) vs. 9.7% (10/103)  Unsteadiness: 0% (0/97) vs. 1.9% (2/103)  Dry mouth: 1.0% (1/97) vs. 2.9% (3/103)  Vertigo: 6.2% (6/97) vs. 1.9% (2/103) | Reports no  funding | Poor |

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| **Author, Year** | **Country Number of Centers and Setting** | **Inclusion Criteria** | **Number Randomized, Analyzed**  **Attrition** | **Intervention** | **Study Participants** | **Duration of Pain (acute, subacute, chronic)** |
| Markman, 2014 | USA  Single center | ≥50 years of age, radiographically  confirmed lumbar spinal stenosis with neurogenic claudication for  ≥3 months (inducible pain ≥4/10 within 15 minutes of treadmill ambulation)  Exclude: Previous pregabalin, prior surgery for lumbar spinal stenosis, vascular disease, movement disorder, neurologic disease impacting ambulation, moderate or severe arthritis of knee or hip, serious medical comorbidities, allergy to diphenhydramine, severe psychiatric disorder | Randomized: 29 (14  vs. 15)  Analyzed: 26 (14 vs.  12)  Attrition: 10% (3/29) | A: Pregabalin: 75 mg po  bid x 3 d, 150 mg bid x 7 d, 75 mg bid x 4 d (n=14)  B: Placebo: Diphenhydramine 6.25 mg po bid x 3 d, 12.5 mg bid x 7 d, 6.25 mg bid x 4 d (n=12)  Each treatment for 2 weeks, with 1 week washout | Mean age: 71 vs. 69  years  Female: 29% vs.  33%  White: 100% vs. 93% Baseline pain with ambulation (mean, 0-  10 NRS): 7.7 vs. 7.1  Baseline RDQ (mean, 0-24): 13 vs.  14 | Chronic (≥3  months): 84% vs.  93% >12 months |

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| **Author, Year** | **Duration of**  **Followup** | **Results** | **Adverse Events Including**  **Withdrawals** | **Funding**  **Source** | **Quality**  **Rating** |
| Markman, 2014 | 10 days  (prior to tapering of each treatment) | A vs. B  Walking distance (mean, m): 237 vs. 261 at 2 w (p=0.35) Pain with ambulation (mean, 0-10 NRS): 7.22 vs. 6.97 at 2 w (p=0.46)  RDQ (mean, 0-24): 13 vs. 11 at 2 w (p=0.01)  Brief Pain Inventory-Short Form, interference (mean, 0-10): 3.7 vs.  3.58 at 2 w (p=0.68)  BPI-SF, pain intensity (mean, 0-10): 4.4 vs. 4.5 at 2 w (p=0.68) ODI (mean, 0-100): 38 vs. 36 at 2 w (p=0.36)  Swiss Spinal Stenosis Questionnaire, symptom severity (mean):  3.09 vs. 2.94 at 2 w (p=0.07)  Swiss Spinal Stenosis Questionnaire, physical function (mean):  2.40 vs. 2.45 at 2 w (p=0.57) | A vs. B  Any adverse events: 64% (19/28) vs.  35% (9/26)  Serious adverse events: None  Withdrawal due to adverse events:  7.1% (2/28) vs. 0% (0/26)  Dizziness: 43% (12/28) vs. 3.8% (1/26) Diarrhea: 11% (3/28) vs. 7.7% (2/26) Somnolence: 18% (5/28) vs. 7.7% (2/26)  Dry mouth: 14% (4/28) vs. 0% (0/26) Nausea: 11% (3/28) vs. 15% (4/26) Edema: 18% (5/28) VS. 7.7% (2/26) | Pfizer Inc. | Fair |

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| **Author, Year** | **Country Number of Centers and Setting** | **Inclusion Criteria** | **Number Randomized, Analyzed**  **Attrition** | **Intervention** | **Study Participants** | **Duration of Pain (acute, subacute, chronic)** |
| Pota, 2012 | Italy  Single center | 35 to 80 years of age, chronic  mechanical-degenerative back pain, symptoms began 12 to 60 months prior, pain ≥50 on 0-100  VAS and >20 on the Pain Rating  Index of the Short-Form McGill  Pain Questionnaire Exclude: Neurological and neuromuscular conditions, other comorbid conditions, hypersensitivity to study drugs, psychiatric disease, HIV infection or other immunodeficiency, skin conditions preventing patch application, cancer-related back pain, pregnant or lactating, renal or liver failure | Randomized: 44 (22  vs. 22) of 44 in run-in period  Analyzed: 44  Attrition: 0% | Buprenorphine run-in  period for 3 weeks, then:  A: Pregabalin 300 mg/day + transdermal buprenorphine 35 mcg/h x 3 w (n=22)  B: Placebo + transdermal buprenorphine 35 mcg/h x 3 w (n=22) | Mean age: 56 years  (overall) Female: 50% (overall)  Race: Not reported  Baseline pain (mean,  0-100 VAS): 35 vs.  32  Baseline function: Not reported | Chronic (12 to 60  months); mean 15 months |

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| **Author, Year** | **Duration of**  **Followup** | **Results** | **Adverse Events Including**  **Withdrawals** | **Funding**  **Source** | **Quality**  **Rating** |
| Pota, 2012 | 3 weeks (at  end of therapy) | A vs. B  Pain (mean, 0-100 VAS): 9.5 vs. 32.8 at 1 w, 6.1 vs. 32.8 at 2 w,  5.7 vs. 33.3 (p<0.05) at 3 w  Short-Form McGill Pain Questionnaire Pain Rating Index (mean, 0-  15): 9.2 vs. 16.5 at 1 w, 4.6 vs. 16.6 at 2 w, 3.7 vs. 16.2 at 3 w  (p<0.05)  SF-MPQ Present Pain Intensity (mean, 0-5): 0.4 vs. 1.7 at 1 w, 0.3 vs. 1.8 at 2 w, 0.3 vs. 2.0 at 3 w  Sleep interference (mean, 0-10): 0.2 vs. 2.3 at 1 w, 0.7 vs. 1.8 at 2 w, 0.6 vs. 1.9 at 3 w (p>0.05)  Acetaminophen use (mean, mg): 46 vs. 636 at w 3 (p<0.05) | A vs. B  Withdrawal due to adverse events: None  Constipation: 23% (5/22) vs. 14% (3/22)  Nausea: 14% (3/22) vs. 14% (3/22) Dizziness: 0% (0/22) vs. 14% (3/22) Somnolence: 18% (4/22) vs. 23% (5/22) | Reports no  funding | Fair |

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| **Author, Year** | **Country Number of Centers and Setting** | **Inclusion Criteria** | **Number Randomized, Analyzed**  **Attrition** | **Intervention** | **Study Participants** | **Duration of Pain (acute, subacute, chronic)** |
| Romano, 2009 | Italy  Single center | 18 to 75 years of age; chronic (>6  months) low back pain due to disc prolapse, lumbar spondylosis, and/or spinal stenosis; pain VAS >40  Exclude: Prior back surgery, diabetes, neurological disease, cardio-renal disease history of gastric ulcers or gastrointestinal bleeding, allergy to study drugs, alcohol or drug abuse | Randomized: 42  Analyzed: 36 (12 vs.  12 vs. 12)  Attrition: 14% (6/42) | A: Pregabalin ~1  mg/kg/d x 1 w, then 2-4 mg/kg/d (mean 2.1 mg/kg/d) (n=12)  B: Celecoxib ~3-6 mg/kg/d (mean 4.2 mg/kg/d) (n=12)  C: Pregabalin + celecoxib (mean 1.78 and 3.75 mg/kg/d) (n=12)  Each treatment for 4 weeks, with 1 week washout prior to crossover | Mean age: 53 years  (overall) Female: 56% (overall)  Race: Not reported Baseline pain: Not reported for initial intervention (mean  45-48)  Baseline function:  Not reported for initial intervention  Disc prolapse: 47% Lumbar spondylosis:  39%  Spinal stenosis: 19% | Chronic (>6  months); mean duration not reported |
| Yaksi, 2007 | Turkey  Single center | Lumbar spinal stenosis (central  or lateral recess) confirmed on  CT or MRI  Exclude: Other pain syndromes | Randomized: 55 (28  vs. 27)  Analyzed: Unclear  Attrition: Not reported | A: Gabapentin: initial  dose 300 mg/day, titrated up to 2400 mg/day (mean not reported) (n=28)  B: No gabapentin (n=27) Both groups also  received exercise,  lumbar corset, and NSAIDS; duration of treatment 4 months | Mean age: 51 vs. 51  years  Female: 79% vs.  56%  Race: Not reported  Baseline pain (mean,  0-10 VAS): 7.0 vs.  6.7  Baseline function: Not reported | Duration not  Specified |

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| **Author, Year** | **Duration of**  **Followup** | **Results** | **Adverse Events Including**  **Withdrawals** | **Funding**  **Source** | **Quality**  **Rating** |
| Romano, 2009 | 4 weeks (at  end of each treatment period) | A vs. B vs. C  Pain (mean, 0-100 VAS): 43 vs. 40 vs. 29 at 4 w (p=0.0001 for A  vs. C and p=0.001 for B vs. C)  Pain reduction: 10% vs. 12% vs. 38% at 4 w  Leeds Assessment of Neuropathic Symptoms and Signs (LANSS)  score <12  Pain (mean, 0-100 VAS): 50.7 vs. 32.5 vs. 32.9 at 4 w (p=0.0002 for A vs. C and p=0.9 for B vs. C)  Pain reduction (estimated from graph): -2.5% vs. 26% vs. 27% at  4 w  LANSS score >12  Pain (mean, 0-100 VAS): 36.3 vs. 32.5 vs. 23.1 (p=0.01 for A vs. C and p=0.0001 for B vs. C)  Pain reduction (estimated from graph): 23% vs. 2% vs. 52% | A vs. B vs. C  Withdrawal due to adverse events: 9% (4/42) overall (not reported by group) Side effects: 14% (5/36) vs. 11% (4/36) vs. 19% (7/36) | Not reported | Fair |
| Yaksi, 2007 | 4 months  (at end of therapy) | A vs. B  Pain (mean, 0-10 VAS): 5.1 vs. 5.6 at 1 month (p=0.40), 4.3 vs. 5.0 at 2 months (p=0.12), 3.6 vs. 4.8 at 3 months (p=0.04), 2.9 vs. 4.7 at 4 months (p=0.006)  Walking distance >1000 meters (estimated from graph): 65% vs. 21%  at 4 meters (p=0.001)  Sensory deficit: 32% (9/28) vs. 63% (17/27) | A vs. B  Withdrawal due to adverse events: None  Ataxia: 7.1% (2/28) vs. not reported | Reports no  Funding | Poor |

**Please see Appendix C. Included Studies for full study references.**