**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 EuropeMulticenter | ≥18 years of age, pain consistentwith 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 periodExclude: 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 (111vs. 107) of 378 in run- in periodAnalyzed: 211 (110 vs.108)Attrition: 14% (31/218) | Placebo run-in period for7 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. 53yearsFemale: 49% vs.55%Race: Not reportedBaseline pain (mean,0-10 VAS): 6.36 vs.6.39Baseline function: Not reported | Chronic (≥3months); 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 (atend of therapy) | A vs. BPain (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 wLoss 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 subscalesHADS 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. BAny 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 | EuropeMulticenter | ≥18 years of age, chronic (≥3months) low back pain requiring a WHO step III analgesic (baseline pain thresholds specified for persons on step I or 2analgesics), painDETECT score for neuropathic pain ≥13 (0 to 38 scale), tapentadol responder during run-in periodExclude: 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 (159vs. 154) of 313 in run- in periodAnalyzed: 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 x1 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. 58yearsFemale: 54% vs.62%White: 99% vs. 100% Baseline pain: 5.9 vs.5.9 (at randomization) Baseline function: Not reported | Chronic (≥ 3months): mean 8.7 vs. 9.4 years |
| Kalita, 2014 | IndiaSingle center | 15 to 65 years of age, low backpain >3 monthsExclude: Chronic low back pain due to a specific cause, immunosuppressant therapy, anticancer drugs, post-transplant, post-spinal surgery, pregnant or breastfeeding, severeneurological deficit due to radiculopathy or spinal stenosis | Randomized: 200 (97vs, 193) Analyzed: 200Attrition: 26% (53/200) | A: Pregabalin: 75 mg bidx 2 w, 150 mg bid x 2 w,300 mg bid, then increased if toleratedand needed (mean dose~430 mg/day) (n=97)B: Amitriptyline: 12.5QHS 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. 42yearsSex: Not reported Race: Not reported Baseline pain: 6.7 vs.6.7Baseline ODI: 42 vs.42Radiculopathy: 47% Spinal stenosis: 6% | Chronic (≥ 3months): 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. BPain (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 at9-10 wPatient 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 wSF-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. BAny 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% | GrunenthalGmbH | Fair |
| Kalita, 2014 | 14 weeks(at end of therapy) | A vs. BPain (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 (955CI 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. BAny 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 nofunding | 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 | USASingle center | ≥50 years of age, radiographicallyconfirmed 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 (14vs. 15)Analyzed: 26 (14 vs.12)Attrition: 10% (3/29) | A: Pregabalin: 75 mg pobid 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. 69yearsFemale: 29% vs.33%White: 100% vs. 93% Baseline pain with ambulation (mean, 0-10 NRS): 7.7 vs. 7.1Baseline RDQ (mean, 0-24): 13 vs.14 | Chronic (≥3months): 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. BWalking 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. BAny adverse events: 64% (19/28) vs.35% (9/26)Serious adverse events: NoneWithdrawal 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 | ItalySingle center | 35 to 80 years of age, chronicmechanical-degenerative back pain, symptoms began 12 to 60 months prior, pain ≥50 on 0-100VAS and >20 on the Pain RatingIndex of the Short-Form McGillPain 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 (22vs. 22) of 44 in run-in periodAnalyzed: 44Attrition: 0% | Buprenorphine run-inperiod 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 reportedBaseline pain (mean,0-100 VAS): 35 vs.32Baseline function: Not reported | Chronic (12 to 60months); 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 (atend of therapy) | A vs. BPain (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 wShort-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 wSleep 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. BWithdrawal due to adverse events: NoneConstipation: 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 nofunding | 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 | ItalySingle center | 18 to 75 years of age; chronic (>6months) low back pain due to disc prolapse, lumbar spondylosis, and/or spinal stenosis; pain VAS >40Exclude: 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: 42Analyzed: 36 (12 vs.12 vs. 12)Attrition: 14% (6/42) | A: Pregabalin ~1mg/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 (mean45-48)Baseline function:Not reported for initial interventionDisc prolapse: 47% Lumbar spondylosis:39%Spinal stenosis: 19% | Chronic (>6months); mean duration not reported |
| Yaksi, 2007 | TurkeySingle center | Lumbar spinal stenosis (centralor lateral recess) confirmed onCT or MRIExclude: Other pain syndromes | Randomized: 55 (28vs. 27)Analyzed: UnclearAttrition: Not reported | A: Gabapentin: initialdose 300 mg/day, titrated up to 2400 mg/day (mean not reported) (n=28)B: No gabapentin (n=27) Both groups alsoreceived exercise,lumbar corset, and NSAIDS; duration of treatment 4 months | Mean age: 51 vs. 51yearsFemale: 79% vs.56%Race: Not reportedBaseline pain (mean,0-10 VAS): 7.0 vs.6.7Baseline function: Not reported | Duration notSpecified |

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| **Author, Year** | **Duration of****Followup** | **Results** | **Adverse Events Including****Withdrawals** | **Funding****Source** | **Quality****Rating** |
| Romano, 2009 | 4 weeks (atend of each treatment period) | A vs. B vs. CPain (mean, 0-100 VAS): 43 vs. 40 vs. 29 at 4 w (p=0.0001 for Avs. C and p=0.001 for B vs. C)Pain reduction: 10% vs. 12% vs. 38% at 4 wLeeds Assessment of Neuropathic Symptoms and Signs (LANSS)score <12Pain (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% at4 wLANSS score >12Pain (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. CWithdrawal 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. BPain (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. BWithdrawal due to adverse events: NoneAtaxia: 7.1% (2/28) vs. not reported | Reports noFunding | Poor |

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