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## Clinical Study Information - Vimpat® (lacosamide)

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Disease area studied	Abbreviated title	Phase	Study ID	Registry database	Study results	Study summary	P
Epilepsy	A Study to Evaluate the Efficacy and Safety of Adjunctive Therapy With Lacosamide in Adults With Partial Onset Seizures	3	Phase EP0008 Completed	NCT01710657 [https://clinicaltrials.gov/ct2/show/study/NCT01710657?term=NCT01710657&rank=1]		[ ]	
Epilepsy	Study to Evaluate the Safety, Tolerability, and Efficacy of Long-term Adjunctive Therapy With Lacosamide in Adults With Partial-onset Seizures	3	Phase EP0009 Ongoing	NCT01832038 [https://clinicaltrials.gov/ct2/show/study/NCT01832038?term=NCT01832038&rank=1]		[ ]	
Epilepsy	Open-label Study to Evaluate the Safety and Tolerability of iv Lacosamide in Japanese Adults With Partial-onset Seizures	3	Phase EP0024 Ongoing	NCT02192814 [https://clinicaltrials.gov/ct2/show/study/NCT02192814?term=NCT02192814&rank=1]		[ ]	
Epilepsy	Long-term Extension Study to Investigate Lacosamide as an Add-on Therapy in Children With Partial Onset Seizures	3	Phase EP0034 Ongoing	NCT01964560 [https://clinicaltrials.gov/ct2/show/study/NCT01964560?term=NCT01964560&rank=1] 2012-005012-26 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2012-005012-26]		[ ]	
Epilepsy	A Trial to Evaluate the Long Term Safety and Tolerability of Lacosamide Taken as Monotherapy in Adults With Partial-onset Seizures	3	Phase EP0057 Ongoing	NCT02124564 [https://clinicaltrials.gov/ct2/show/study/NCT02124564?term=NCT02124564&rank=1]		[ ]	
Epilepsy	To Determine Tolerability and Efficacy of Long-term Oral Lacosamide in Patients With Partial Seizures	2	Phase SP0615 Completed	NCT00552305 [https://clinicaltrials.gov/ct2/show/study/NCT00552305?term=NCT00552305&rank=1]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00552305?term=NCT00552305&rank=1]	[ ]	
Epilepsy	A Trial to Investigate the Safety, Tolerability and Pharmacokinetics of Intravenous SPM 927 (n/a)	2	Phase SP0616 Completed	NCT00800215 [https://clinicaltrials.gov/ct2/show/study/NCT00800215?term=NCT00800215&rank=1]	PDF	[ ]	B 2
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Disease area studied	Abbreviated title	Phase	Study ID	Registry database	Study results	Study summary	P
Neuropathic Pain	An Open-label Continuation Trial to Assess the Continued Efficacy and Safety of Ascending Doses of Lacosamide in Subjects With Chronic Refractory Neuropathic Pain	2	Completed	Phase SP0647 NCT00237458 [https://clinicaltrials.gov/ct2/show/study/NCT00237458?term=NCT00237458&rank=1]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00237458?term=NCT00237458&rank=1]		M N P.
Neuropathic Pain	An Open-label follow-on Trial to Assess the Long-term Safety and Efficacy of Oral SPM 927 in Subjects With Diabetic Neuropathy	2	Completed	Phase SP0665 NCT00861042 [https://clinicaltrials.gov/ct2/show/NCT00861042?term=NCT00861042&rank=1]		[]	SI P.
Postherpetic Neuralgia	An Open-Label Follow-on Trial to Assess the Long-Term Safety and Efficacy of Oral SPM 927 in Subjects With Postherpetic Neuralgia (PHN)	2	Completed	Phase SP0690 NCT00238511 [https://clinicaltrials.gov/ct2/show/study/NCT00238511?term=NCT00238511&rank=1]	PDF	[]	
Neuropathic Pain	A Trial to Assess the Efficacy and Safety of SPM 927 in Subjects With Painful Distal Diabetic Neuropathy	2	Completed	Phase SP0742 NCT00235469 [https://clinicaltrials.gov/ct2/show/study/NCT00235469?term=NCT00235469&rank=1]	PDF	[]	W 2
Neuropathic Pain	A Trial to Assess the Efficacy and Safety of SPM 927 (Lacosamide) in Subjects With Painful Distal Diabetic Neuropathy	3	Completed	Phase SP0743 NCT00238524 [https://clinicaltrials.gov/ct2/show/study/NCT00238524?term=NCT00238524&rank=1]	PDF	[]	Z C
Neuropathic Pain	A Follow-On Trial to Assess the Long Term Safety and Efficacy of SPM 927 in Painful Distal Diabetic Neuropathy	2	Completed	Phase SP0745 NCT00235443 [https://clinicaltrials.gov/ct2/show/study/NCT00235443?term=NCT00235443&rank=1]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00235443?term=NCT00235443&rank=1]	[]	G N 1) 1: Fe N (E 2)
Neuropathic Pain	Study Evaluating Long-term Safety and Efficacy of Lacosamide in Subjects With Painful Distal Diabetic Neuropathy.	3	Completed	Phase SP0746 NCT00546351 [https://clinicaltrials.gov/ct2/show/study/NCT00546351?term=NCT00546351&rank=1] 2004-000551-42 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2004-000551-42]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00546351?term=NCT00546351&rank=1]	[]	B P. S- Sc A (A A  H N 3. o Fe N (E 2)

Disease area studied	Abbreviated title	Phase	Study ID	Registry database	Study results	Study summary	P
Epilepsy	SPM 927 (400mg/Day and 600mg/Day) as Adjunctive Therapy in Subjects With Partial Seizures With or Without Secondary Generalization	3	Phase SP0754 Completed	NCT00136019 [https://clinicaltrials.gov/ct2/show/study/NCT00136019?term=NCT00136019&rank=1]	PDF	PDF	C 21
Epilepsy	A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel Group Trial to Investigate the Efficacy and Safety of SPM 927 (200mg/Day and 400mg/Day) as Adjunctive Therapy in Subjects With Partial Seizures With or Without Secondary Generalization	3	Phase SP0755 Completed	NCT00220415 [https://clinicaltrials.gov/ct2/show/study/NCT00220415?term=NCT00220415&rank=1]	PDF	PDF	H 21
Epilepsy	Determine Safety and Efficacy of Long-term Oral Lacosamide in Patients With Partial Seizures	3	Phase SP0756 Completed	NCT00522275 [https://clinicaltrials.gov/ct2/show/study/NCT00522275?term=NCT00522275&rank=1]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00522275?term=NCT00522275&rank=1]	[]	H 21
Epilepsy	Safety and Tolerability of Intravenous SPM 927 as Replacement for Oral SPM 927 in Subjects With Partial Seizures	3	Phase SP0757 Completed	NCT00151879 [https://clinicaltrials.gov/ct2/show/study/NCT00151879?term=NCT00151879&rank=1] 2004-002322-22 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2004-002322-22]	PDF	[]	Ki 21
Neuropathic Pain	Trial to Assess the Efficacy and Safety of SPM 927 (200, 400, and 600mg/Day) in Subjects With Painful Distal Diabetic Neuropathy	3	Phase SP0768 Completed	NCT00135109 [https://clinicaltrials.gov/ct2/show/study/NCT00135109?term=NCT00135109&rank=1]	PDF	[]	Si 21
Epilepsy	Assess Safety and Efficacy of Lacosamide in Patients With Partial Seizures	3	Phase SP0774 Completed	NCT00515619 [https://clinicaltrials.gov/ct2/show/study/NCT00515619?term=NCT00515619&rank=1] 2004-000152-16 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2004-000152-16]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00515619?term=NCT00515619&rank=1]	[]	
Neuropathic Pain	A Trial to Assess the Long-term Safety and Efficacy of Lacosamide in Subjects With Painful Diabetic Neuropathy	3	Phase SP0830 Completed	NCT00220337 [https://clinicaltrials.gov/ct2/show/study/NCT00220337?term=NCT00220337&rank=1] 2004-000960-28 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2004-000960-28]	PDF	[]	Si P S C Ei IA Si 21
Epilepsy	A Multicenter, Open-Label Study To Investigate The	2	Phase SP0847 Completed	NCT00938431 [https://clinicaltrials.gov/ct2/show/study/NCT00938431?term=NCT00938431&rank=1] 2011-001558-27		[]	

Disease area studied	Abbreviated title	Phase	Study ID	Registry database	Study results	Study summary	P
	Safety And Pharmacokinetics Of Lacosamide In Children With Partial Seizures			[https://www.clinicaltrialsregister.eu/ctr-search/search?query=2011-001558-27]			
Epilepsy	An Open-Label Study to Determine Safety, Tolerability, and Efficacy of Oral Lacosamide in Children With Epilepsy	Phase 2	SP0848	NCT00938912 [https://clinicaltrials.gov/ct2/show/study/NCT00938912?term=NCT00938912&rank=1] 2011-001559-35 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2011-001559-35]		[]	
Neuropathic Pain	A Trial to Assess the Efficacy and Safety of 400mg/Day Lacosamide in Subjects With Painful Diabetic Neuropathy	Phase 3	SP0874	NCT00350103 [https://clinicaltrials.gov/ct2/show/study/NCT00350103?term=NCT00350103&rank=1] 2005-005788-27 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2005-005788-27]	PDF	[]	B N S; M N (A 2)
Fibromyalgia	Assessing Efficacy and Safety of Lacosamide Compared to Placebo in Reducing Signs and Symptoms of Fibromyalgia Syndrome.	Phase 2	SP0887	NCT00401830 [https://clinicaltrials.gov/ct2/show/study/NCT00401830?term=NCT00401830&rank=1]	[https://clinicaltrials.gov/ct2/show/results/NCT00401830?term=NCT00401830&rank=1]	[]	D C 1: 6: th S; 3 U
Epilepsy	Trial to Demonstrate the Efficacy and Safety of Conversion to Lacosamide Monotherapy for Partial-onset Seizures (ALEX-MT)	Phase 3	SP0902	NCT00520741 [https://clinicaltrials.gov/ct2/show/study/NCT00520741?term=NCT00520741&rank=1] 2007-005439-27 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2007-005439-27]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00520741?term=NCT00520741&rank=1]	[]	W E] -
Epilepsy	Long-term Lacosamide (LCM) Monotherapy Use and Safety of Monotherapy and Adjunctive Therapy for Partial-onset Seizures	Phase 3	SP0904	NCT00530855 [https://clinicaltrials.gov/ct2/show/study/NCT00530855?term=NCT00530855&rank=1] 2007-005440-25 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2007-005440-25]		[]	
Osteoarthritis	Trial to Assess Efficacy and Safety of Lacosamide in Subjects With Osteoarthritis of the Knee	Phase 2	SP0905	NCT00485472 [https://clinicaltrials.gov/ct2/show/study/NCT00485472?term=NCT00485472&rank=1] 2006-005048-97 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2006-005048-97]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00485472?term=NCT00485472&rank=1]	[]	D C 1: 6: th S; 3 U
Migraine disorders	A Study Designed to Test the Effectiveness and Safety of Treating Patients With Lacosamide for Migraine Prophylaxis	Phase 2	SP0906	NCT00440518 [https://clinicaltrials.gov/ct2/show/study/NCT00440518?term=NCT00440518&rank=1]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00440518?term=NCT00440518&rank=1]	[]	D C 1: 6: th S; 3 U

Disease area studied	Abbreviated title	Phase	Study ID	Registry database	Study results	Study summary	P
Epilepsy	Safety of Intravenous Lacosamide Dose Followed by Twice Daily Oral Lacosamide in Subjects With Partial-onset Seizures	3	Completed	Phase SP0925 NCT00655551 [https://clinicaltrials.gov/ct2/show/study/NCT00655551?term=NCT00655551&rank=1]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00655551?term=NCT00655551&rank=1]	[]	Fc 2i
Epilepsy	Study to Assess the Long-term Safety of Oral Lacosamide in Subjects With Partial-onset Seizures	3	Completed	Phase SP0926 NCT00655486 [https://clinicaltrials.gov/ct2/show/study/NCT00655486?term=NCT00655486&rank=1]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00655486?term=NCT00655486&rank=1]	[]	Le 2i lr C 2i 2i
Epilepsy	Trial to Assess Lacosamide as the First add-on Anti-epileptic Drug Treatment in Patients With Partial-onset Seizures	4	Completed	Phase SP0954 NCT00955357 [https://clinicaltrials.gov/ct2/show/study/NCT00955357?term=NCT00955357&rank=1] 2009-011181-28 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2009-011181-28]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT00955357?term=NCT00955357&rank=1]	[]	
Epilepsy	Open-Label Study to Assess Lacosamide Safety as Add-on Therapy for Primary Generalized Tonic-Clonic Seizures in Subjects With Epilepsy	2	Completed	Phase SP0961 NCT01118949 [https://clinicaltrials.gov/ct2/show/study/NCT01118949?term=NCT01118949&rank=1]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT01118949?term=NCT01118949&rank=1]	[]	W C 6i th 3i 2i
Epilepsy	Open-Label Extension Study to Assess the Safety and Seizure Frequency Associated With Lacosamide for Primary Generalized Tonic-Clonic Seizures in Subjects With Idiopathic Generalized Epilepsy	2	Completed	Phase SP0962 NCT01118962 [https://clinicaltrials.gov/ct2/show/study/NCT01118962?term=NCT01118962&rank=1]	LINK [https://clinicaltrials.gov/ct2/show/results/NCT01118962?term=NCT01118962&rank=1]	[]	Yi C 2i o 3i U
Epilepsy	A Study to Investigate the Safety and Efficacy of Lacosamide Added to the Patients Current Therapy in Patients Aged 1 Month to less than 18 Years Old With Epilepsy Syndromes Associated With Generalized Seizures.	3	Ongoing	Phase SP0966 NCT01969851 [https://clinicaltrials.gov/ct2/show/study/NCT01969851?term=NCT01969851&rank=1] 2012-001446-18 [https://www.clinicaltrialsregister.eu/ctr-search/search?query=2012-001446-18]		[]	
Epilepsy	Study to Investigate Lacosamide as	3	Ongoing	Phase SP0969 NCT01921205 [https://clinicaltrials.gov/ct2/show/study/NCT01921205?term=NCT01921205&rank=1]		[]	

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