Product Name	Vimpat® 50 & 100mg film-coated tablets
Active substance	Lacosamide (LCM)
Indication and conditions of use	In general, indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent (16-18 years) patients with epilepsy. For the Medical Need Program, , partial-onset or generalized tonic-clonic seizures in patients > 16 years-old, for patients that received LCM in SP0994 at the time of study unblinding and close of SP0994, and who benefited from the treatment per investigator assessment In general, lacosamide must be taken twice a day (usually once in the morning and once in the evening). Patients will start on the individual LCM dose that they had reached at the completion of the previous monotherapy study. LCM will be administered orally twice daily (at approximately 12 hour intervals in the morning and in the evening) in 2 divided. Lacosamide treatment may also be initiated with a single loading dose of 200 mg, followed approximately 12 hours later by a 100 mg twice daily (200 mg/day) maintenance dose regimen. A loading dose may be initiated in patients in situations when the physician determines that rapid attainment of lacosamide steady state plasma concentration and therapeutic effect is warranted. It should be administered under medical supervision with consideration of the potential for increased incidence of central nervous system adverse reactions. Administration of a loading dose has not been studied in acute conditions such as status epilepticus. Lacosamide is taken by oral route
Conditions, delays and further rules for participation of patients	The treating physician will note the points below and use appropriate clinical judgment when deciding if LCM is a suitable therapy for the patient to continue. The treating physician should only continue patients on LCM if he/she believes that LCM is the most effective treatment for the patient. Patients must fulfill all of the following inclusion criteria: - The patient is not eligible for a clinical trial running with Lacosamid and/or a clinical trial running in the envisaged indication (monotherapy) of this program." - Patient has completed the Termination Visit of SP0994 and has been treated with LCM monotherapy. - Patient is expected to benefit from participation in the MNP with LCM monotherapy in the opinion of the treating physician. - Patient is willing and able to comply with all program requirements. - Patient is informed of the details of this MNP, is given ample time and opportunity to ask questions and consider his/her participation in this MNP, and the patient or the legally authorized representative (LAR) has provided verbal consent to participate, and, if applicable to local regulations, has given written informed consent. Exclusion criteria: Patients will not be enrolled in the MNP with LCM in any of the following situations: - 1. Patient is receiving any investigational drugs or using any experimental devices in addition to LCM - 2. Patient requires another AED for the treatment of seizures - 3. Patient experienced emergence of a seizure type other than partial-onset or generalized tonic-clonic seizures, or occurrence of status epilepticus - 4. Patient developed second- or third-degree atrioventricular (AV) block

	or another clinically relevant change in medical condition (or ECG or laboratory parameter) - 5. Patient having liver function test (LFT) results of transaminases (aspartate aminotransferase [AST] and/or alanine aminotransferase [ALT]) ≥ 5×upper limit of normal (ULN) or ≥ 3xULN when total Bilirubin ≥ 2xULN - - 6. Patient has actual suicidal ideation or behavior - 7. Patient is experiencing an ongoing serious AE (SAE) and there is no expected benefit for him/her to continue on LCM treatment. - 8. Female patient who is pregnant or nursing, and/or a woman of childbearing potential who is not surgically sterile, 2 year postmenopausal or does not practice one highly effective method of contraception (according to ICH guidance defined as those that result in a failure rate of less than 1% per year when used consistently and correctly), unless sexually abstinent, for the duration of the study. - 9. Patient was treated with carbamazepine controlled release (CBZ-CR) in SP0994. Withdrawal: In accordance with current clinical practice, if LCM has to be discontinued, it is recommended this be done gradually. Patients who require an anti-epileptic drug in addition to LCM and who qualified for commercial LCM (being reimbursed) must exit the MNP and may continue receiving LCM for add-on therapy prescribed by the treating physician. Female patients should be instructed to inform the treating physician of any changes in protection methods or inform the physician if she intends to become pregnant. The treating physician should consider withdrawing LCM treatment when informed by a female patient of the intention to become pregnant. Should a patient become pregnant, UCB Drug Safety (DS) department should be informed immediately. There are no adequate data from the use of LCM in pregnant women. Studies in animals did not indicate any teratogenic effects in rats or rabbits, but embryotoxicity was observed in rats and rabbits at maternal toxic doses. The potential risk for humans is unknown.

Duration of the program	The program will start once it is approved by the FAMHP.. Eligible patients are accepted as soon as the program is authorized. The turnaround time is 24/48hrs and the same for escalation time Concerning the date when the program will end: this program allows patients to continue with the same treatment until marketing application for LCM is approved and LCM is commercially available for monotherapy in Belgium, or UCB has determined that the medical need program for the monotherapy indication will be formally discontinued.
Conditions of distribution	Patients will receive the medicinal product from the treating physician, starting on the individual LCM des when they have completed the previous monotherapy study.
Responsible of the program	The responsible person is: UCB BioPharma S.P.R.L. Allée de la Recherche 60 1070 Brussels Belgium **The contact person for program-related enquiries is:** Fabienne Dubois Email: Fabienne.Dubois@ucb.com Phone: + 32 2 559 95 43 44 **The contact person for regulatory affairs-related enquiries is:** Clinigen Regulatory Affairs department Email: regulatory@clinigengroup.com Phone: + 44 1283 49 5010
Modalities for the disposal	If a kit is not used or only partially used, the treating physician (or pharmacist) may re-dispense all unused medication but only to the designated named patent to whom that kit has been allocated. If a patient discontinues the treatment with LCM the treating physician informs Clinigen. The physician will return all unused supplied LCM to Clinigen warehouse or designee or ensure its destruction at the facility.

The information for registration of suspected unexpected serious adverse reactions

The table below is extracted from the current IB for LCM and depicts the list of observed (and thus expected) ADRs:

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Investigator's Brochure Lacosamide

MedDRA® Primary System Organ Class	MedDRA® Preferred Term
Cardiac disorders	Uncommon: first-degree atrioventricular block Rare: second-degree atrioventricular block
Ear and labyrinth disorders	Common: vertigo,
Eye disorders	Very common: diplopia Common:
Gastrointestinal disorders	Very common: nausea Common: vomiting, constipation, flatulence, dyspepsia,
General disorders and administration site conditions	Common: gait disturbance, asthenia, fatigue, irritability, feeling drunk
Injury	Common: fall, skin laceration, contusion[a]
Musculoskeletal and connective tissue disorders	Common: muscle
Nervous system disorders	Very common: dizziness, headache Common: cognitive disorder, nystagmus, balance disorder, coordination abnormal, memory impairment[b], tremor, somnolence, dysarthria, disturbance in attention, hypoaesthesia,
Psychiatric disorders	Common: depression, confusional state, insomnia
Skin and subcutaneous tissue disorders	Common: pruritus, rash[a]

ADR=adverse drug reaction; CCDS=Company Core Data Sheet; DNP=diabetic neuropathic pain; MedDRA®=Medical Dictionary for Regulatory Activities; PI= package insert: SPC=summary of product characteristics; US=United States
Note: Classifications according to the following: Very Common – incidence ≥10%; Common – incidence
≥1% and <10%; Uncommon – incidence ≥0.1% and <1%; Rare – incidence <0.1%