

# EULEV - Effectiveness and Use of Levetiracetam in Real Life

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## Général

### Identification

Nom détaillé Effectiveness and Use of Levetiracetam in Real Life

Sigle ou acronyme EULEV

Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.) CCTIRS 04.198, CNIL 904498

### Thématiques générales

Domaine médical Neurology  
Psychology and psychiatry

Déterminants de santé Iatrogenic  
Medicine

Mots-clés Levetiracetam, prescribing patterns, effectiveness, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

### Responsable(s) scientifique(s)

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## Collaborations

## Financements

Financements	Mixed
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Précisions	Laboratoire UCB Pharma (soutien inconditionnel) - UCB Pharma (unconditional support) - Inserm
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## Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur	INSERM
Statut de l'organisation	Secteur Public

## Contact(s) supplémentaire(s)

## Caractéristiques

## Type de base de données

Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Longitudinal study (except cohorts)
Origine du recrutement des participants	A selection of health institutions and services
Critère de sélection des participants	Medication(s) taken
Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle	No

## Informations complémentaires concernant la constitution de l'échantillon

Two parallel and complementary studies have been implemented. An observational study was conducted among a sample of hospital and non-hospital neurologists who were to retrospectively include over two periods 1000 patients who had received a first prescription of levetiracetam (between 1 January and 31 August 2005, or between January 1 and August 31, 2006 for the second period). For each inclusion period, all neurologists registered in the "Cegecim" database were invited by post to participate in the study. In parallel, a study based on the EPIB sample from the SNIIRAM database was performed using two extractions of anonymised data of patients who had at least one reimbursement of levetiracetam between 1 July 2004 and 31 August 2005 for the first extraction and between 1 July 2005 and 31 August 2006 for the second. The study based on the EPIB sample allowed the verification of the field study sample validity and to collect information independently of the field study.

## Objectif de la base de données

### Objectif principal

The objectives of this study were to describe patients initiating treatment with levetiracetam, the prescribing patterns, and to evaluate the effectiveness of levetiracetam in a real-life situation in terms of treatment retention over one year.

### Critères d'inclusion

Patients who initiated treatment with levetiracetam between 01/01/2005 and 31/08/2005 or between 01/01/2006 and 31/08/2006 (irrespective of whether or not treatment was continued), and having never previously been treated with levetiracetam; patient agreeing to participate; patient can be followed over the next 12 months; Patient not participating in a clinical trial (Huriet-Sérusclat).

## Type de population

### Age

Newborns (birth to 28 days)  
Infant (28 days to 2 years)  
Early childhood (2 to 5 years)  
Childhood (6 to 13 years)  
Adolescence (13 to 18 years)  
Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)  
Elderly (65 to 79 years)  
Great age (80 years and more)

Population concernée	Sick population
Sexe	Male Woman
Champ géographique	National
Détail du champ géographique	Hospital and non-hospital neurologists in metropolitan France
<b>Collecte</b>	
<b>Dates</b>	
Année du premier recueil	2006
Année du dernier recueil	2008
<b>Taille de la base de données</b>	
Taille de la base de données (en nombre d'individus)	[500-1000[ individuals
Détail du nombre d'individus	858
<b>Données</b>	
Activité de la base	Data collection completed
Type de données recueillies	Clinical data
Données cliniques, précisions	Direct physical measures
Existence d'une bibliothèque	No
Paramètres de santé étudiés	Health event/morbidity Health event/mortality Health care consumption and services
Consommation de soins, précisions	Hospitalization Medical/paramedical consultation Medicines consumption
<b>Modalités</b>	
Mode de recueil des données	Included patients were the subject of collection of indirectly personal medical data (patient questionnaire completed by the neurologist) at inclusion, at each follow-up visit, and at one year of follow-up or in case of discontinuation of levetiracetam data will be collected for all patients.

Suivi des participants	Yes
Détail du suivi	Levetiracetam-treated patients were followed for a period of one year (from date of levetiracetam initiation).

Appariement avec des sources administratives	No
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## Valorisation et accès

### Valorisation et accès

Lien vers le document	<a href="http://www.ncbi.nlm.nih.gov/pubmed?term=eulev%20NOT%20eulevp&amp;cmd=correctspelling">http://www.ncbi.nlm.nih.gov/pubmed?term=eulev%20NOT%20eulevp&amp;cmd=correctspelling</a>
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Description	List of publications in Pubmed
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### Accès

Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	A final study report was submitted to the funder. The final study report and scientific communications (posters, articles, ...) are validated by the study Scientific Committee. Ownership of study data is the subject of an agreement between the University of Bordeaux Segalen and the funder. Terms for third-party access to the database are to be defined.
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Accès aux données agrégées	Access on specific project only
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Accès aux données individuelles	Access on specific project only
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