

# MENUI - Cohort of children with isolated nocturnal enuresis : a study of the safety of Minirinmelt in actual prescription

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| General                                                                                                                  |                                                                                                                   |
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| Identification                                                                                                           |                                                                                                                   |
| Detailed name                                                                                                            | Cohort of children with isolated nocturnal enuresis : a study of the safety of Minirinmelt in actual prescription |
| Sign or acronym                                                                                                          | MENUI                                                                                                             |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CCTIRS (04/06/07), CNIL n°907222 (30/10/07)                                                                       |
| General Aspects                                                                                                          |                                                                                                                   |
| Medical area                                                                                                             | Endocrinology and metabolism<br>Urology, andrology and nephrology                                                 |
| Others (details)                                                                                                         | Isolated nocturnal enuresis                                                                                       |
| Keywords                                                                                                                 | desmopressin, Minirin® tablet, Minirinmelt®                                                                       |
| Scientific investigator(s)<br>(Contact)                                                                                  |                                                                                                                   |
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| Unit                                                                                                                     | Laboratoire FERRING S.A.S                                                                                         |
| Collaborations                                                                                                           |                                                                                                                   |
| Funding                                                                                                                  |                                                                                                                   |
| Funding status                                                                                                           | Private                                                                                                           |
| Details                                                                                                                  | FERRING S.A.S                                                                                                     |

| Governance of the database                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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| Sponsor(s) or organisation(s) responsible                              | Laboratoire FERRING SAS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Organisation status                                                    | Private                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Additional contact                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Main features                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Type of database                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Type of database                                                       | Study databases                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Study databases (details)                                              | Longitudinal study (except cohorts)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Database recruitment is carried out by an intermediary                 | A selection of health institutions and services                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Database recruitment is made on the basis of:                          | Medication(s) taken                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Database recruitment is carried out as part of an interventional study | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Additional information regarding sample selection.                     | Using the survey base, a preliminary list of 830 doctors (415 pediatricians and 415 general practitioners) will be compiled by random drawing. A letter presenting the survey along with a detailed synopsis of the project and a response coupon will be sent to each doctor on this list. Interested doctors will return the response coupon. If the response rate is insufficient, contacting doctors who have not responded may be considered. If the number of positive responses is too high, a random drawing from the interested doctors will be conducted, complying with the defined proportion of general practitioners and pediatricians. If the number is insufficient, an additional list of doctors will be randomly selected from the survey base described hereinabove, still in compliance with the defined proportion. |
| Database objective                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Main objective                                                         | Show that the two oral forms (tablet and lyophilisate) of desmopressin have a similar safety profile and in particular in terms of frequency of the symptoms of alarms of an intoxication via water, in actual prescription situations, i.e. at general                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

practitioners.

#### Inclusion criteria

##### Criteria for inclusion:

- patient having an isolated nocturnal enuresis, defined by the number of wet nights per week,
- patient aged 6 to 18 years,
- patient in which the family doctor has decided to prescribe a treatment via desmopressin, or Minirin® tablets or Minirinmelt® lyophilisate.

##### Criteria for non-inclusion:

- patient who has already received prior treatment via desmopressin regardless of its form,
- patient who has a treatment in progress via desmopressin,
- patient participating in a therapeutic study.

#### Population type

##### Age

Childhood (6 to 13 years)  
Adolescence (13 to 18 years)

##### Population covered

Sick population

##### Gender

Male  
Woman

##### Geography area

National

##### Detail of the geography area

Metropolitan France

#### Data collection

##### Dates

Date of first collection (YYYY or MM/YYYY)

2007

Date of last collection (YYYY or MM/YYYY)

2010

##### Size of the database

Size of the database (number of individuals)

[500-1000[ individuals

Details of the number of individuals

750

#### Data

Database activity

Data collection completed

|                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Type of data collected                | Clinical data<br>Declarative data<br>Biological data                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Clinical data (detail)                | Direct physical measures                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Declarative data (detail)             | Paper self-questionnaire<br>Face to face interview                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Biological data (detail)              | Natremia collected in the case of an undesirable event if this was requested by the doctor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Presence of a biobank                 | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Health parameters studied             | Quality of life/health perception<br>Others                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Other (detail)                        | Profile of the patients treated, description of the impact of isolated nocturnal enuresis in patients treated and their families, description of the methods for use of Minirin® tablets and Minirinmelt® lyophilisate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Procedures                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Data collection method                | Data collected in a paper observation notebook by the doctor using the data from the patient's medical dossier and following the information collected during consultations of the child with his or her parents or legal guardian. Satisfaction of the parents and of the children as well as the information pertaining to the quality of life of the patients (supplemented by the children and by the parents) were collected during the consultations via the filling out of the self-questionnaires at inclusions and when the treatment was stopped for the study.                                                                                                                                      |
| Participant monitoring                | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Details on monitoring of participants | Each patient was followed in the study for a maximum period of 9 months after inclusion. The rate of visits was that of the consultations as normally practiced by the doctors. Following the inclusion the patient was followed for a period referred to as the desmopressin posology adaptation period, until the effective or maximum posology has been reached. This was then followed by a treatment period for the retained posology (1st cure). If the patient benefitted from a 2nd cure of desmopressin, the information was collected by the doctor until the end of the treatment. At each consultation, the doctor checked if the patient had any undesirable events. If so, the doctor filled out |

the undesirable event collection form and then faxed it to the pharmacovigilance department of Ferring S.A.S. Each serious or non-serious undesirable event was follow-up until its end.

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| Links to administrative sources                                                       | No                                                                                                                                                                                                |
| Promotion and access                                                                  |                                                                                                                                                                                                   |
| Promotion                                                                             |                                                                                                                                                                                                   |
| Access                                                                                |                                                                                                                                                                                                   |
| Terms of data access (charter for data provision, format of data, availability delay) | Methods for accessing the results: study report, submitted congress abstract, publication: manuscript currently being drafted.<br>Methods for accessing the database are currently being defined. |
| Access to aggregated data                                                             | Access on specific project only                                                                                                                                                                   |
| Access to individual data                                                             | Access on specific project only                                                                                                                                                                   |