European real-Life use of Eludril eXtra among 4 countries (ELEX4)

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000986

Study ID

1000000986

DARWIN EU® study

No

Study countries

- Bulgaria
- Greece
- Poland
- Portugal

Study description

Chlorhexidine 0.2% mouthrinse (Eludril Extra) is widely used in dentistry as an adjunct to mechanical plaque control for the prevention and management of gingivitis, periodontitis, peri-implant mucositis, and other oral conditions. Oral health is strongly influenced by systemic diseases such as diabetes and cancer, as well as pregnancy and lifestyle factors, and is associated with a significant impact on quality of life.

This study aimed to evaluate the impact of CHX 0.2% in routine clinical practice on oral health-related quality of life (OHRQoL), as well as treatment use, compliance, and patient and dentist satisfaction. Particular attention was given to special-interest populations, including pregnant women, diabetic patients, oncological patients, and patients with peri-implant mucositis.

This was a prospective, longitudinal, observational cohort study conducted in four European countries (Bulgaria, Greece, Poland, and Portugal). Adult patients prescribed CHX 0.2% mouthrinse as part of routine dental care were included after the prescribing decision made by the dentist. Treatment initiation and follow-up were fully driven by routine clinical practice, without any intervention from the study protocol.

Data were collected at baseline and at a single follow-up visit between 10-20 days. Collected variables included socio-demographic characteristics, medical history, oral health status, clinical parameters, treatment patterns, compliance, and satisfaction. Oral health status was assessed using clinical indicators such as bleeding on probing, gingival inflammation, and plaque index (Silness-Löe Index). OHRQoL was measured using the validated Oral Health Impact Profile-5 (OHIP-5).

The primary endpoint was the change in OHRQoL (OHIP-5 score) between baseline and follow-up. Secondary endpoints included description of real-world use of CHX 0.2%, patient compliance, and patient and dentist satisfaction with treatment. A total of 408 patients were included in the analysis.

Study status

Finalised

Research institutions and networks

Institutions

Pierre Fabre Oral Care

Contact details

Study institution contact

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Primary lead investigator

Jean-Noel Vergnes

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/11/2024

Actual: 04/11/2024

Study start date

Planned: 01/04/2025

Actual: 15/02/2025

Data analysis start date

Planned: 01/10/2025

Actual: 28/10/2025

Date of final study report
Planned: 30/11/2025

Actual: 12/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pierre Fabre Oral Care

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Study design:

Prospective, longitudinal, multicentre observational cohort study conducted in four European countries (Bulgaria, Greece, Poland, Portugal) in routine dental practice, assessing CHX 0.2% (Eludril Extra) use with baseline and 10–20 day follow-up.

Main study objective:

The main objective is to evaluate the impact of the real-life use of Eludril Extra on the patients' oral health-related quality-of-life in four European countries

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ELUDRIL

Medicinal product name, other

Eludril extra

Study drug International non-proprietary name (INN) or common name

CHLORHEXIDINE DIGLUCONATE SOLUTION

Population studied

Short description of the study population

The study population will include adult patients (≥18 years) from routine dental care in four European countries (Bulgaria, Greece, Poland, and Portugal) who are eligible for chlorhexidine 0.2% mouthrinse (Eludril Extra) and initiating the treatment at the time of inclusion. Patients will have received the study information and provided non-opposition to the use of their anonymised data. The decision to prescribe chlorhexidine 0.2% mouthrinse remains entirely at the discretion of the treating dentist and is made independently of the study. The prescription therefore precedes patient inclusion, and participation in the study does not modify the clinician's usual practice or influence patient management. Patients will be followed under routine clinical practice conditions, with no intervention from the study protocol. Only patients with at least one follow-up visit between 10 and 20 days after treatment initiation are eligible for analysis. Patients will be excluded if they are already participating in another clinical study involving oral health products, are under legal guardianship or curatorship, have known contraindications to chlorhexidine use (including hypersensitivity to the active substance or formulation excipients), or are unable to complete study assessments as required by the protocol, including

the follow-up visit.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Special population of interest

Other

Pregnant women

Special population of interest, other

Diabetic patients, oncological patients and patients with peri-implant mucositis

Estimated number of subjects

400

Study design details

Setting

This study was conducted in routine dental care settings across four European countries: Bulgaria, Greece, Poland, and Portugal. Patients were managed in primary dental practices and dental care centers participating in the study. Investigating dentists were selected through national dental practice registries

using a random and/or network-based recruitment process, ensuring representation of real-life dental practice conditions in each country.The study population consisted of adult patients (≥18 years) for whom the initiation of Eludril Extra (chlorhexidine 0.2% mouthwash) was decided solely by the treating dentist as part of routine care. The decision to prescribe Eludril Extra was independent of study participation, and patients were invited to participate only after the therapeutic decision had been made, without any impact on clinical management.Eligible patients were those initiating Eludril Extra and agreeing to participate in the study and to the anonymised use of their data. Only patients with a planned follow-up visit between 10 and 20 days after baseline were included in the analysis, reflecting real-life short-term follow-up in dental practice.Exclusion criteria included patients already enrolled in another clinical study on oral health products, patients with contraindications to mouthwash use (e.g. known allergy to chlorhexidine or excipients), and patients under legal guardianship or curatorship. Patients unable to provide informed non-opposition or to comply with routine follow-up were also excluded.The study period comprised an 8-month recruitment phase in 2025 and a short individual follow-up period of 10 to 20 days per patient. Data were collected at two time points: at baseline (treatment initiation) and at follow-up during routine dental care.This was a non-interventional, single-cohort observational study with no comparator group, conducted under real-world conditions reflecting routine clinical practice.

Outcomes

Outcomes related to the objectives are:

- Main outcome:

The primary endpoint is the change in oral health-related quality of life between baseline and follow-up, assessed using the Oral Health Impact Profile-5 (OHIP-5) questionnaire. This validated instrument evaluates the impact of oral conditions

on patients' quality of life and is measured at inclusion and at 10 -20 days follow-up.

Secondary outcomes:

Secondary endpoints are related to the description of real-life use of Eludril Extra, clinical evolution, compliance, and satisfaction.

-Description of patients using Eludril Extra, including socio-demographic and clinical characteristics at baseline (sex, age, socio-professional category, BMI, comorbidities, and reason for consultation);

- Oral health status at baseline and follow-up, including dental status and pregnancy-related characteristics;

- Changes in oral health parameters between baseline and follow-up: bleeding on probing, bleeding during tooth brushing, gingival inflammation, and plaque index (Silness-Löe Index);

- Oral care characteristics at baseline and follow-up, including previous periodontal treatment, number of dental visits in the previous year, and treatments performed during the study period;

- Eludril Extra use characteristics: indication, daily frequency of use, duration, and concomitant treatments at baseline and follow-up;

- Patient compliance assessed at follow-up based on patient report (regular use yes/no and reasons for non-use) and dentist assessment (good / not good / not assessable);

- Treatment satisfaction assessed at follow-up using a Visual Analog Scale (VAS), evaluating: patient satisfaction regarding Eludril Extra use and oral health management in real-life conditions and dentist satisfaction regarding suitability of Eludril Extra for patient management in routine practice.

Data analysis plan

Data management and statistical analyses will be performed using SAS software (version 9.4 or later). Analyses will be conducted on the full analysis

set including all eligible patients with available baseline and follow-up data. A flow chart will describe the study population at each stage.Descriptive analyses will summarize socio-demographic, clinical, and treatment characteristics. Categorical variables will be described using frequencies and percentages, while continuous variables will be summarized using mean, standard deviation, median, minimum, and maximum values.The primary endpoint (change in OHIP-5 score between baseline and follow-up) will be analysed using a paired Student’s t-test. If normality assumptions are not met, a Wilcoxon signed-rank test will be used. Results will be presented with corresponding confidence intervals and p-values. Changes in OHIP-5 subdomains will also be explored.Secondary endpoints will be analysed descriptively. Changes in clinical parameters (bleeding on probing, gingival inflammation, bleeding during tooth brushing, and Silness-Löe plaque index) between baseline and follow-up will be assessed using paired statistical tests (t-test or Wilcoxon as appropriate). Compliance and satisfaction will be summarized descriptively.Subgroup analyses will be performed in predefined populations (pregnant women, diabetic patients, oncological patients, cardiovascular disease patients, and patients with peri-implant mucositis).Statistical significance will be set at $p < 0.05$. No formal hypothesis testing adjustment for multiplicity is planned, as analyses are exploratory and descriptive in this real-world observational study.Internal validity will be supported by standardized data collection procedures and validated questionnaires (OHIP-5). External validity is ensured by the multicountry real-life design reflecting routine dental practice.

Summary results

A total of 28 dentists from four European countries (Bulgaria, Greece, Poland, and Portugal) participated in the study, of whom 24 recruited at least one patient. Overall, 426 patients were enrolled, and 408 completed follow-up and were included in the final analysis. At baseline, the mean age was 48.3 years and 64.5% were female. Periodontal conditions were highly prevalent, including

periodontitis (47.5%) and gingivitis (37.7%), with some patients presenting comorbidities such as diabetes, cardiovascular disease, cancer, or peri-implant mucositis.

The mean follow-up period was 15.9 days. Significant improvements in oral health parameters were observed, with bleeding on probing decreasing from 83.6% to 27.7%, bleeding during brushing from 66.4% to 10.8%, and gingival inflammation from 85.3% to 24.8%. The Silness-Löe plaque index also decreased significantly. Improvements were consistent across subgroups, including patients with comorbidities.

Oral health-related quality of life (OHIP-5) improved significantly, with mean scores decreasing from 5.6 to 1.9 ($p<0.0001$), across all dimensions. Compliance with Eludril Extra was high (~95%), and both patient and dentist satisfaction were strong.

Overall, real-life use of Eludril Extra was associated with improved periodontal outcomes, quality of life, and high treatment satisfaction in routine dental practice.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Non-interventional study

Patient surveys

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable