Lay Summary of Clinical Study results

Lay language title	Performance and safety study with Petit Drill in children
Full study title	The performance and safety of Petit Drill in the French paediatric population: a post-marketed clinical follow-up study
Registry Number	NCT06688370
Therapeutic area	Otorhinolaryngology
Disease	Throat irritation associated with dry cough
Study Phase	Post-marketing / Real-Word-Evidence study
Final version	30 September 2025

This document is a summary of study results and conclusions written for public and people who took part in the study. This summary was finalised on 17 December 2025.

For people who took part in the study, Pierre Fabre Pharmaceutical group would like to say:

THANK YOU

We hope this document helps you understand your key role in medical research.
If you have questions about the results, please speak with the doctor or staff at your study site.

Please note that:

- These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.
- This summary reflects the results of one single study and that other studies may show other results.

Specific terms used in this lay summary may be found in the Glossary of Pierre Fabre

You can click below to find the following information:

1 What was the reason for the study?

This study was conducted to collect information about the syrup Petit Drill® in a real-life context. Petit Drill® syrup is indicated for throat irritation (sore throat) associated with dry cough. The study was done with children from 6 months to 6 years old.
The study aimed to describe the performance and the safety of Petit Drill®. Performance means how Petit Drill® achieve to alleviate throat irritation associated with dry cough.

The main objective of this study was to describe the performance of Petit Drill® syrup.
The secondary objectives were:

- To describe the characteristics of the people using Petit Drill®
- To describe the benefit of Petit Drill® regarding nighly cough, cough severity, and quality of life
- To describe if Petit Drill® was well tolerated

2 How was the study conducted?

This was an observational study conducted in France. An observational study looks at how the product tested works in everyday life. This type of study does not have strict conditions to be included like in clinical interventional trials, as the aim is to reflect real life.
As Petit Drill® is available in pharmacies, pharmacists managed the people contact. Pharmacists also checked the criteria to enter in the study.
People were treated according to routine practice. No additional intervention or visit was required.
Parents or legal guardians completed questionnaires via a mobile application.
Participants were treated for 3 days.

3 When and where the study was conducted

The study started on 14 March 2024 (first participant included) and was completed on 7 November 2024 (last participant included). The study was conducted in France.

4 Who took part in the study?

Which participants took part in the study?

- Boys or girls, 6 months to 6 years of age
- With Petit Drill® bought in a pharmacy
- With acute dry cough lasting < 48 hours
- With a score ≥ 3 at least for 3 of the 5 items of Pediatric Cough Questionnaire (PCQ)*
- With Petit Drill® used at the usual dose during the 3 days of treatment

** PCQ is a questionnaire assessing how the nightly cough impact child and parents' life.*

How many participants took part in the study?

12 children took part in the study, 7 were girls and 5 were boys.

How old were the participants?

The average age of the participants was 3 years old.

5 What was the study treatment?

Participants took Petit Drill® syrup bought in pharmacy. The dose received was the usual recommended one.
During the study, the doses taken was: 2-4 doses on the first day, then 3 to 4 doses on the second day and the third day.

6 What were the side effects and adverse events?

Participants could have medical problems unexpected during the study. These medical problems may or may not be caused by medical device used which is the syrup Petit Drill®. They are named adverse events. If these adverse events are caused by Petit Drill®, they are named side effects.

What side effects did participants experience?

2 participants experienced a total of 4 side effects/special situation caused by the syrup Petit Drill®.

One participant experienced vomiting and cough due to Petit Drill®, and another participant was exposed to Petit Drill® use error leading to underdose.

Side effect/special situation due to Petit Drill®	Number of participants (% out of 12 participants)
Participant who experienced side effects/special situations*	2 (16.7%)
Participant who experienced serious** side effects	0 (0%)
Participants who stopped the treatment because of side effects	0 (0%)

= participants

* Special situation: correspond to abnormal situation, error use

** Among these side effects, some of them could be serious. A side effect is serious when:
- The participant needs hospital care,
- The participant's life is in danger,
- It causes lasting problems or,
- It is medically important in the Doctor's opinion.

What adverse events did participants have?

In addition to the side effects already described above, 2 participants had 3 adverse events (not caused by the device) during the study:

- Tonsil inflammation and fatigue in one participant and,
- Throat pain in another participant.

None of these adverse events was serious.

7 What were the study results?

The study was prematurely stopped due to difficulty in recruiting participants in the study. 245 were initially planned, and finally 12 participants were included.

Performance of Petit Drill® using a Paediatric Cough Questionnaire

To test the performance of Petit Drill®, a Paediatric Cough Questionnaire was completed. The score obtained at baseline and after 3 days of treatment was evaluated. Lower was the score, better was the past night.
The total decreased rapidly over time, with at least a 3-point reduction achieved in all 7 patients for which the score could be analysed.

Adherence to Petit Drill®

The adherence to Petit Drill® was assessed by the daily consumption of Petit Drill ®. Adherence means the number of times the treatment was administered compared to number of times it was planned to be administered. All parents reported administrating Petit Drill® on the first day but did not all systematically specify the number of doses. Adherence was optimal on the second day with:

- Most participants (6 out of 9) receiving 3 doses, and,
- 1 participant receiving 4 doses as per the recommended regimen.

One parent continued to give the treatment beyond the recommended 3 day-treatment period.

Parent's satisfaction with Petit Drill®

The parents' satisfaction with Petit Drill® was assessed using a brief 6-question questionnaire, to be completed at 2-day or at 3-day treatment.
Results showed that among the 9 answers from the parents (3 were missing):

- All parents (9 out of 9, 100%) were satisfied with the information provided by the Petit Drill® instruction for use
- All parents (9 out of 9, 100%) reported the ease of Petit Drill® use and the feeling that children enjoyed the taste of the syrup
- The quality of therapeutic management was rated as good (5 out of 9, 56%) to excellent (2 out of 9, 22%)
- Most parents (7 out of 9, 77.8%) would recommend the syrup
- Most parents (6 out of 9, 67%) reported that Petit Drill® effectively met their child's needs.

8 Further information

Are there plans for further studies?

No study is planned.

Where can you learn more about this study?

You can find more information about this study on the website:www.ClinicalTrials.gov