Lay Protocol Synopsis

Lay language title:	Performance and safety study with Petit Drill in children
Full study title:	The performance and safety study of Petit Drill in the French paediatric population: a post-marketed clinical follow-up
Registry Number:	NCT06688370

1 What is the reason for the study?

Throat irritation associated with dry cough in children under 6 years are currently treated with soothing substances.
Petit Drill® syrup is indicated for throat irritation (sore throat) associated with dry cough. People treated should have from 6 months of age and up to 6 years.
Petit Drill® was initially marked by Pierre Fabre in 2013.
The aim of this study was to get information in a real-life context. This study aimed to describe the performance and the safety of Petit Drill® in children with throat irritation associated with dry cough. Performance means how Petit Drill® achieve to alleviate throat irritation associated with dry cough.

2 What are the objectives of the study?

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

3 How is 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. Since Petit Drill® is delivered in pharmacies, pharmacists managed the people contact. Pharmacists also checked the criteria to enter in the study. One clinical centre based in France managed the study.
People were treated according to routine practice. No additional intervention or visit was required.
Parent or legal guardian completed questionnaires via a mobile application.
Participants were treated for 3 days.

4 Who could take part in the study?

The study took place in France.
The following people could participate 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.*

5 What is the study treatment and how is it administered?

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

6 Ethical considerations

This study has been conducted according to ethical considerations and has followed the rules for conducting such study. The study started only after it was approved. People provided their consent to participate in the study.

7 What are the possible benefits and risks in taking part in the study?

People took Petit Drill® according to the usual routine practice. Information about the benefits and risks are available in the notice of Petit Drill®.