Lay Summary of Clinical Study results

Lay language title	An observational study with Structum® in osteoarthritis
Full trial title	A Prospective Non-Interventional Study on STRUctum® in Adult Patients with oSTeoarthritis – TRUST
Registry Number	NCT06623773
Therapeutic area	Rheumatology
Disease	Arthrosis
Study Phase	Post-marketing / Real-Word-Evidence study
Final version	17 December 2025

This document is a summary of study results and conclusions written for the public and people who took part in the study. This summary was finalized on 17 December 2025.
The information in this summary does not include additional information available after this date.

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:

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1 What was the reason for the study?

Osteoarthritis or arthrosis is a disorder that can affect any joint of the body, like the knees. Osteoarthritis may result in pain, stiffness and loss of movement. Many treatments are available to reduce pain due to osteoarthritis.
Among these treatments, there are drugs termed chondroprotective. Chondroprotective drugs help protect cartilage by slowing down cartilage breakdown and helping it regenerate. They improve symptoms of osteoarthritis like pain and stiffness. Chondroitin sulfate is a natural chondroprotective substance present in the joints of the body. Structum® is a drug containing chondroitin.
This study aims to understand how people live with knee osteoarthritis and how chondroitin sulfate may help improve their daily life.

The primary objective was to describe the characteristics of the people treated with Structum®. The severity of their knee osteoarthritis was also described. The severity was evaluated using a questionnaire named: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

The secondary objectives were to describe over 6-month follow-up:

- The severity of the knee osteoarthritis
- The burden associated with knee osteoarthritis using a questionnaire named BONe'S
- The general health and quality of life using a questionnaire named SF-12
- How many people were taking Structum®

- How people were satisfied with Structum®

2 How was the study conducted?

The study was an observational, real-world study conducted over a 6-month period.

Observational means doctors do not change the usual care of the participants. They only collect information during usual visits. No extra tests or visits were required for the study. People usually have 2 follow-up visits: after 3 months and after 6 months. People had to fill out 4 questionnaires at each visit related to the severity of the disease, its burden, general health, quality of life, and their level of satisfaction with Structum®.

This study was carried out in people for whom Structum® was prescribed by their doctor.

3 When and where the trial was conducted

The study started on 12 July 2023 (first participant included) and was completed on 28 October 2024 (last visit of the last participant included). The study was conducted in Poland.

4 Who took part in the study?

Which participants took part in the study?

People that fulfilled the following criteria could participate in the study:

- Adults aged 50 to 85 years (because knee osteoarthritis is more common in this age group)
- Diagnosed with knee osteoarthritis
- Treated with Structum®
- With dosage of osteoarthritis pain medication stable at least one week prior to study entry, if any

How many participants took part in the study?

136 people took part in the study, 93 were women and 43 were men.

How old were the participants?

The average age of the participants was 65 years.

5 What were the trial treatments?

Participants took Structum® daily prescribed by their doctor. The dose received was the one prescribed in accordance with local clinical practice.

6 What were the adverse events and the side effects?

What adverse events did participants have?

Participants may have unwanted medical problems during the study. These medical problems may or may not be caused by Structum®. They are named adverse events.

In total, 10 adverse events occurred in 9 participants out of 136 participants.

Adverse events	Structum® (out of 136 participants)
Drug ineffective	3 (2.2%)
Joint pain	2 (1.5%)
Spinal pain	2 (1.5%)
Abdominal pain upper	1 (0.7%)
Dizziness	1 (0.7%)
Malaise	1 (0.7%)

= participants

What side effects did participants have?

Side effects are adverse events reported in the study that are considered to be caused by the drug used, in this case Structum®.

4 participants reported one side effect each.

None of these 4 side effects was 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.

Participants	**Structum® (out of 136 participants)**
Participant who had side effects	4 (2.9%)
Participant who had serious side effects	0 (0%)
Participants who had corrective treatment	0 (0%)
Participants who had decreased treatment dosage because of side effects	2 (1.5%)
Participants who stopped the treatment because of side effects	2 (1.5%)

= participants

- The table below shows the 4 side effects reported in 4 participants.

Side effects	**Structum® (out of 136 participants)**
Drug ineffective	2 (1.5%)
Malaise	1 (0.7%)
Upper abdominal pain	1 (0.7%)

= participants

Most of the side effects were of moderate intensity and did not lead to treatment stopped.

7 What were the study results?

136 participants participated in the study. Among them, 124 participants completed the study. All participants were prescribed with 1 g/day of Structum®. For most of the participants (131/136, 96.3%), it was the first prescription of Structum®.
A total of 36/136 (27%) participants received previous treatment for knee osteaoarthritis.

Osteoarthritis symptoms severity measured by the questionnaire WOMAC
The total WOMAC questionnaire score may range from 0 to 2400. Higher scores indicating worse pain, stiffness, and functional limitations.
At entry in the study, participants had a mean WOMAC score = 1158.
At 3 months, the total score decreased and the difference from the study entry was -392. At 6 months, the difference from the study entry was -626.

Osteoarthritis burden measured by the questionnaire BONe'S
The total Burden Osteoarthritis News Scale (BONe'S) questionnaire score may range from 0 to 100 scale. Higher scores represent a heavier burden.
At entry in the study, participants had a mean BONe'S score = 36.
At 3 months, the total score decreased and the difference from the study entry was -10. At 6 months, the difference from the study entry was -16.

General health measured by the questionnaire SF-12
The score for the physical or mental health of the Short Form Questionnaire (SF-12) questionnaire may range from 0 to 100. Higher score indicates a better health functioning.
At entry in the study, participants had a mean for the physical health score = 36. At 3 months, the score increased and the difference from the study entry was 5. At 6 months, the difference from the study entry was 7.
At entry in the study, participants had a mean for the mental health score = 44. At 3 months, the score increased and the difference from the study entry was 4. At 6 months, the difference from the study entry was 7.

Structum® treatment persistence
Most people continued taking Structum® during the study, with no missed capsules at 3 months (118/132 participants, 89.4%), and at 6 months (118/130 participants, 90.8%).

Participant satisfaction with Structum® treatment

A questionnaire was completed by the participants, with a global satisfaction score that could range from 0 to 100. A higher score indicates a better satisfaction. The global satisfaction score was 72 out of 100 at 3 months, and 75 out of 100 at 6 months.

8 Further information

Are there plans for further studies?

No study is planned with Structum® in osteoarthritis.

Where can you learn more about this study?

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