

SDN-CTR-LAYSUM-04

**If you are a participant who took part in the clinical trial, thank you for your time and commitment. You made the clinical trial possible.  
Thank you for helping us on our way to bringing medicines to patients.**

## **1 TRIAL NAME**

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**Brief trial name:** A comparison of how much tapentadol is in the bloodstream of healthy men after taking different tablets on a full stomach

**Protocol number:** HP5503-93

**Universal trial number:** U1111-1202-5348

## **2 WHO SPONSORED THIS TRIAL?**

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Grünenthal GmbH.

## **3 GENERAL INFORMATION ABOUT THE CLINICAL TRIAL**

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The main aim of this clinical trial was to find out if the amount of tapentadol in the bloodstream was similar after taking 2 tapentadol PR 25 mg tablets or 1 tapentadol PR 50 mg tablet. The tablets were taken on a full stomach.

Another aim of the trial was to find out if both the tapentadol PR 25 mg tablet and the tapentadol PR 50 mg tablet are equally well tolerated.

The clinical trial began on 07 May 2018 and ended on 26 Jul 2018.

## **4 WHO WAS INCLUDED IN THIS TRIAL?**

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40 healthy men were treated in the Netherlands.

The youngest was 18 years old and the oldest was 50 years old. The average (mean) age was 23.8 years.

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Participants in this clinical trial had to meet predefined criteria to ensure that it was safe for them to receive tapentadol, that the results of the clinical trial were valid, and that the laws and regulations were followed.

## **5 WHICH MEDICINES WERE STUDIED?**

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Each participant received 2 tapentadol PR 25 mg tablets once and 1 tapentadol PR 50 mg tablet once.

## **6 WHAT WERE THE OVERALL RESULTS OF THE TRIAL?**

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The amount of tapentadol found in the blood was similar after taking 2 tapentadol PR 25 mg tablets or 1 tapentadol PR 50 mg tablet on a full stomach.

Some participants experienced side effects during the trial that could be linked to the trial medicine according to the trial doctor. About 1 out of 3 participants experienced such effects. The number of participants with side effects was about the same after taking 2 tablets of 25 mg tapentadol PR or 1 tablet of 50 mg tapentadol PR.

The most common side effects were drowsiness, fatigue, and dizziness.

No new side effects were reported in this trial.

The results described in this report are for one clinical trial. The findings of other clinical trials might be different. How well tapentadol works and how safe it is to use must not be judged on the results of one clinical trial alone.

If you have questions, please contact your family doctor.