



# CLINICAL TRIAL RESULTS

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

**Sponsor:** Pfizer, Inc.

**Medicine(s) Studied:** Ibuprofen

**Protocol Number:** B3491013

**Dates of Trial:** 17 November 2014 to 27 May 2015

**Title of this Trial:** Actual Use Trial of Ibuprofen 400 mg

[A Multicenter Actual Use and Compliance Study of Ibuprofen 400 mg in a Simulated Over-The-Counter Environment]

**Date of this Report:** 07 August 2017

**– Thank You –**

Pfizer, the Sponsor, would like to thank you for your participation in this clinical trial and provide you a summary of results representing everyone who participated. If you have any questions about the study or results, please contact the doctor or staff at your study site.

## WHY WAS THIS STUDY DONE?

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Medication to ease minor aches and pains can be purchased in stores without a doctor's permission ("over the counter"). Every package of an over-the-counter (OTC) medication has instructions for how much medication should be taken in a day (24 hours). Even with these instructions, patients may not take enough medication, or may take too much medication. If patients do not take enough medication, their pain may not go away, or their pain may come back sooner than expected. If patients take too much medication, they may experience medical problems.

Ibuprofen is a non-steroidal anti-inflammatory (NSAID) medication that can be bought OTC and used to ease pain caused by colds, headaches, toothaches, muscle aches, cramping due to monthly periods, and backaches, as well as minor arthritis (swelling of the joints) pain. Ibuprofen can also be used to temporarily reduce fevers. NSAIDs block substances in the body that make chemicals that signal pain. When these substances are blocked, patients won't feel as much pain.

Information on the package of ibuprofen available in stores tells patients to take no more than 1 or 2 pills (200-400 mg) every 4 to 6 hours. The package also tells patients that they should not take more than 6 pills in a day. It is important that patients not take more medication than is suggested on the package instructions. Taking too much ibuprofen may result in problems such as nausea or stomach pain, upset, or bleeding.

Researchers have developed a different dose (study dose) of ibuprofen (400 mg) that patients cannot yet buy in stores. Researchers think that the study dose might be easier to use than the dose that can be purchased now (200 mg) because patients won't have to take as many pills to ease their pain. This chart compares the dose of ibuprofen that is available now (200 mg) to the study dose (400 mg):

<b>Ibuprofen</b>		
<b>Dose</b>	<b>How Many Pills Should I Take? How Often Should I Take Them?</b>	<b>How Many Pills Can I Take in a Day?</b>
<b>Dose Available Now</b>		
200 mg	1 or 2 pills every 4 to 6 hours	6 (maximum dose of 1200 mg)
<b>Study Dose</b>		
400 mg	1 pill every 6 to 8 hours	3 (maximum dose of 1200 mg)

Researchers did this study to find out if patients who decide to purchase this study dose of ibuprofen will take the correct number of the 400 mg caplets. For this study, researchers wanted to answer the question: Will patients who decide to buy the 400 mg caplets follow the instructions on the package and take the correct amount of medication?

## **WHAT HAPPENED DURING THE STUDY?**

This study looked at a single group of patients who had used OTC pain relievers to treat minor aches and pains in the past. Researchers wanted to find out how many patients who decided to buy the study dose of ibuprofen (400 mg) in a drug store setting would follow the directions on the medication package and take no more than 3 caplets in a day.

This study included adult men and women who:

- Took medication to ease pain or reduce fevers at least 5 times a month for the 3 months before the study started;
- Did not experience health issues when taking ibuprofen;
- Did not have a history of stomach ulcers (sores) or bleeding problems; and
- Were not taking blood thinners or steroids.

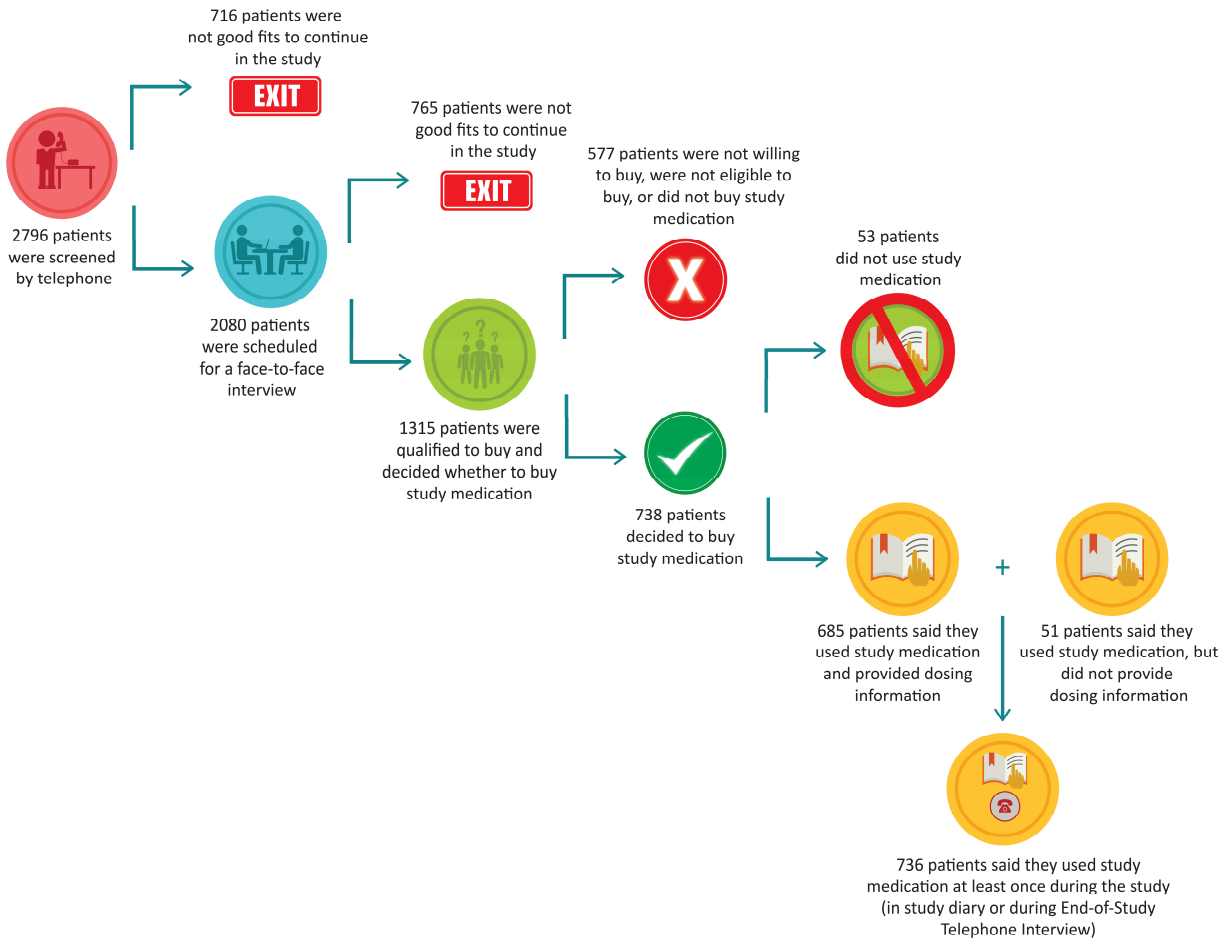
Patients who used OTC pain relievers to treat minor aches and pains were instructed to call a toll-free number if they wanted to join the study. After patients called the number, researchers asked them questions to find out if they were a good fit for the study. Patients who were a good fit and wanted to join the study were sent to a study drug store where they would be able to buy the study dose of ibuprofen. At the pharmacy, patients were given an empty ibuprofen 400 mg caplet package, were asked to read the information on the outside of the package, and were then asked if they would like to buy the medication. The researchers allowed patients to buy the medication if it was safe for them to use it to treat their minor aches and pain.

Patients who decided to buy the medication were asked to keep a diary for 30 days. They were asked to write the number of caplets they took, the time at which they took the caplets, and the date on which they took the caplets in the diary. At the end of the 30 days, the patients were asked to return the diary and all medication that they didn't use to the researchers. After researchers received the diary and medication, they called the patients on the phone and asked them, among other things:

- If they had any medical problems during the 30 days of the study;
- If they took any medication (other than study medication) to help with these medical problems;
- How much medication they took; and
- How often they took the medication.

After the patients talked to the researchers on the phone, they were allowed to exit the study.

This diagram shows what happened to patients in this study:



While patients were only in the study for 30 days, the entire study took about 6 months to complete. This study was run at 25 locations in the United States. It began on 17 November 2014 and ended on 27 May 2015. A total of 326 men and 412 women decided to buy the medication. All patients were between the ages of 19 and 87.

Patients were supposed to be in the study for 30 days. Of the 738 patients who started the study (decided to buy the medication), 635 finished the study. A total of 103 patients left before the study was over. Of these 103 patients who did not complete the study, 68 did not follow the study instructions (violated the protocol) and were asked to drop out. Some of these patients who violated the protocol did not return their diaries; as a result, the doctor/researchers could not figure out how much study medication they took.

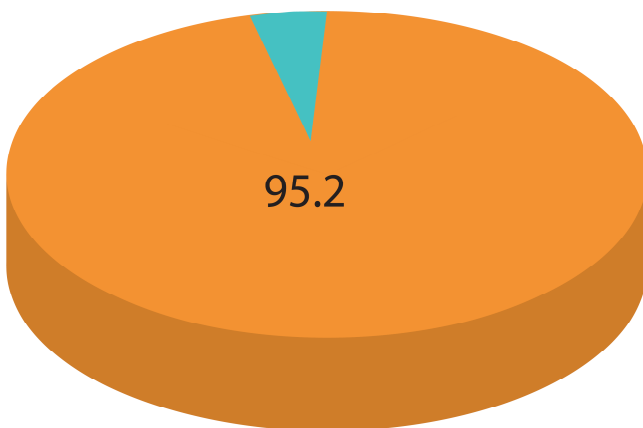
When the study ended in May 2015, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

## WHAT WERE THE RESULTS OF THE STUDY?

**Did patients follow the directions on the package of the study dose (400 mg) of ibuprofen and take the correct number of caplets each day?**

**Most patients followed the directions on the package of the study dose (400 mg) of ibuprofen and took the correct number of caplets each day.**

Researchers wanted to know if patients would take more than 3 caplets of ibuprofen 400 mg in a single day (24 hours). More than 9 out of every 10 patients (around 95%) never took more than 3 caplets a day or only did so on 2 or fewer days during the 30-day study. The patients who did take more than 3 caplets a day did so because their healthcare professional told them that they could. Based on these results, researchers concluded that patients were able to follow the directions on the package and were able to take the correct amount of medication.



Percentage of patients never taking more than 3 caplets in a day or doing so on no more than 2 days of the 30-day study

This does not mean that everyone in this study had these results, and individual results could have been better or worse than the overall group. Other studies may find different results. These are just some of the main findings of the study, and more information may be available at the websites listed at the end of this summary.

## **WHAT MEDICAL PROBLEMS DID PARTICIPANTS HAVE DURING THE STUDY?**

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The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could have been caused by a study treatment, or by another drug the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what the medical problems of an experimental drug dose might be.

A total of 76 out of 736 patients who said that they took the study dose of ibuprofen at least one time during the study had at least 1 non-serious medical problem. A total of 2 patients left the study due to medical problems. The most common medical problems are listed below.



## Most Common Medical Problems (Reported by 3 or More Patients)

Medical Problem	Ibuprofen 400 mg (736 Patients treated)
Common cold (Nasopharyngitis)	8 (1.1%)
Heartburn (Gastroesophageal reflux disease)	4 (0.5%)
Dizziness	4 (0.5%)
Constipation	3 (0.4%)
Nausea	3 (0.4%)
Flu (Influenza)	3 (0.4%)
Cut (Laceration)	3 (0.4%)
Headache	3 (0.4%)

## WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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A medical problem is considered “serious” when it is life-threatening, causes lasting problems, or needs hospital care.

A total of 6 patients (0.8%, or 6 out of 736 patients) had serious medical problems.

No patients died during the study. None of the 6 serious medical problems was reported by more than 1 patient. These included blocked coronary (heart) artery (coronary artery occlusion), atypical pneumonia (not caused by a type of bacteria that usually causes pneumonia [lung infection]), infection of the inner layers of the skin (cellulitis), pneumonia, joint dislocation, and kidney stone (nephrolithiasis). Only



coronary artery occlusion was considered by the doctors and the Sponsor to be related to the study medicine.

## **WHERE CAN I LEARN MORE ABOUT THIS STUDY?**

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

The full scientific report of this study is available online at:

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Use the study identifier **NCT02294019**

Please remember that researchers look at the results of many studies to find out which medicines work best and are safest for patients. No further clinical trials with this study dose of ibuprofen are planned at this time.

**Again, thank you for volunteering.  
We do research to try to find the  
best ways to help patients, and you  
helped us to do that!**