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/Acetaminophen

Protocol Number: B5061004

Dates of Trial: 31 August 2016 to 01 February 2017

Title of this Trial: A Phase 3, Double-Blind, Randomized Safety and Efficacy Study Comparing Multiple Administrations of IBU 250 mg/APAP 500 mg (Administered as Two Tablets of IBU/APAP 125 mg/250 mg) to Placebo in the Treatment of Post Surgical Dental Pain in Adult Subjects

Date of this Report: 13 September 2018

– 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?

Ibuprofen and acetaminophen are 2 medications commonly used for relieving pain and fever. Both of these medications can be bought without a doctor's prescription ("over the counter"), but they work in slightly different ways. Ibuprofen works by blocking chemicals called "prostaglandins" that the body makes when it is injured or in pain. Researchers think that acetaminophen works by blocking certain prostaglandins that are found in the central nervous system.

Some patients might not get enough pain relief from taking either ibuprofen or acetaminophen alone. Also, taking higher doses of ibuprofen or acetaminophen can cause unwanted medical problems, such as liver problems or stomach damage and bleeding, without giving patients greater pain relief.

The main purpose of this study was to find out whether a new study drug that combines low doses of ibuprofen and acetaminophen together in the same tablet ("study drug") could relieve pain better than "placebo" (looks just like the study drug, but with no medicine). For this study, the dose was 2 tablets that provided ibuprofen 250 mg and acetaminophen 500 mg. Researchers wanted to know:

- Would patients who took the study drug have more pain relief after dental extraction, compared to patients who took the placebo?

"Dental extraction" means having teeth removed. To answer this question, researchers asked patients to rate their pain, using a scale of 0 (no pain) to 10 (worst pain).

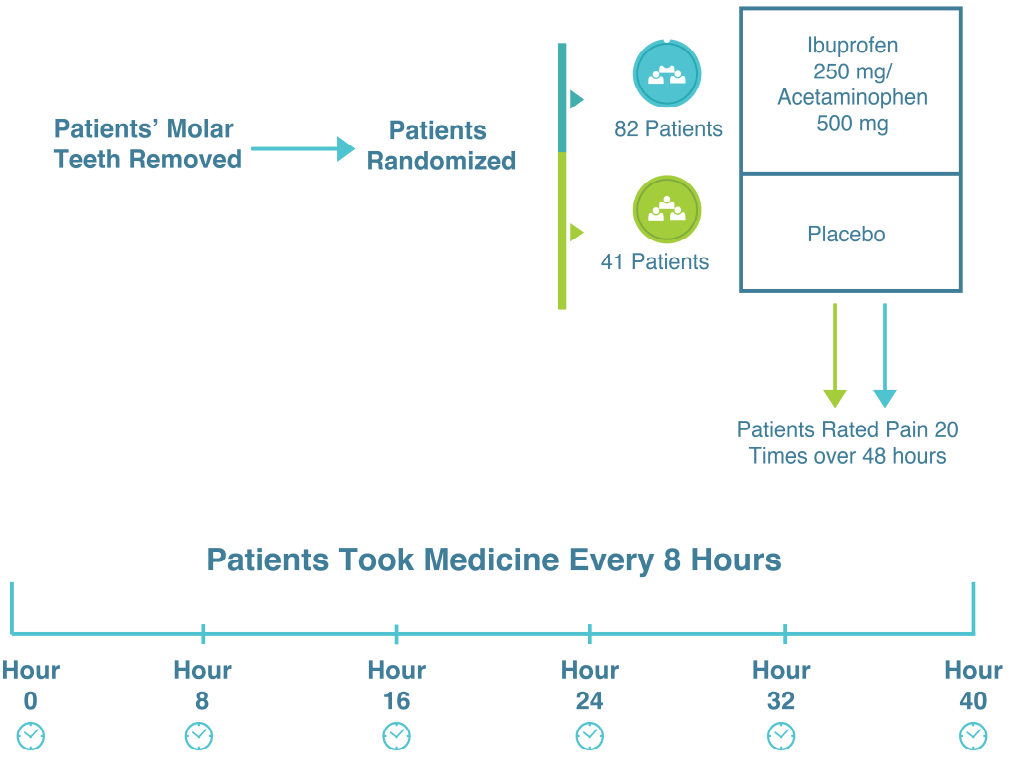
WHAT HAPPENED DURING THE STUDY?

All the patients in this study had a dental extraction. The researchers divided the patients into 2 groups, and gave each group a different study treatment. One group took the study drug, which combines ibuprofen and acetaminophen together in the same tablet, and the other group took a placebo. A placebo does not have any medicine in it, but looks just like the study treatment. Patients were picked for each treatment group by chance alone. This is known as a "randomized" study, and it helps make the treatment groups more even to compare.

The patients and researchers did not know who took the study drug and who took the placebo. This is known as a "double-blind" study. Researchers use this type of study to make sure that the results are not influenced in any way.

After their dental extraction, the patients rested quietly at the study center. Patients were given their first dose of study treatment once they reported having at least moderate pain. They received another dose of medicine every 8 hours for the next 48 hours. Patients were also asked to rate their pain 20 times over the 48 hours following their dental extraction.

The graph below shows what happened during this study.



This study included healthy young adults who had at least 3 third molar teeth ("wisdom teeth") extracted. Third molar teeth are a type of teeth found in the back of the mouth. All patients were between the ages of 18 and 38 years old, and 56 men and 67 women participated in the study.

While individual patients were only in the study for about 48 hours, the entire study took about 5 months to complete. Patients joined the study at 1 location in the United States. It began 31 August 2016 and ended 1 February 2017.

Of the 123 patients who started the study, 112 completed it. Eleven (11) patients did not finish the study by their own choice or because they had a medical problem.

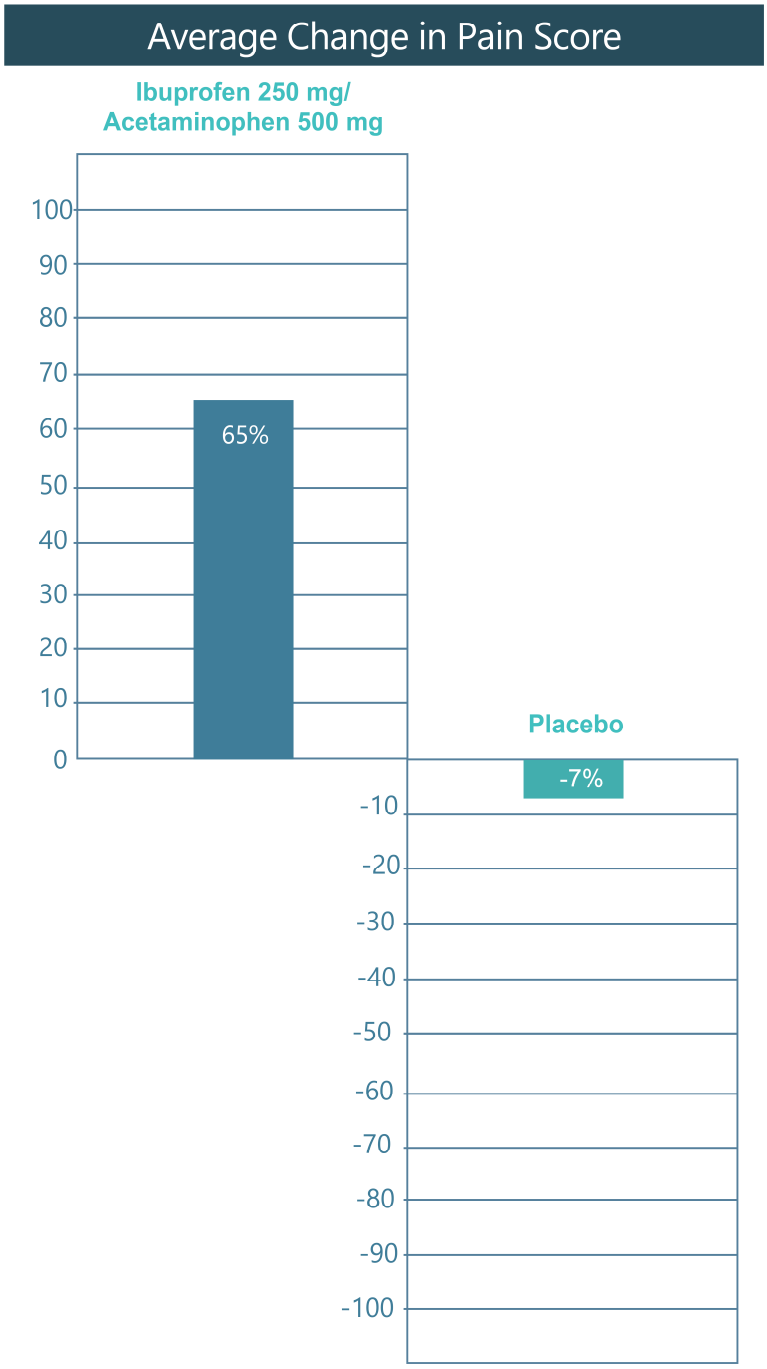
When the study ended in February 2017, the study Sponsor (company that designed and paid for the study) began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

WHAT WERE THE RESULTS OF THE STUDY?

Did patients who took the study drug that combines ibuprofen and acetaminophen together in the same tablet have more pain relief after dental extraction compared to patients who took placebo?

Yes. 82 patients were assigned to take the study drug, and 41 patients were assigned to take placebo. Patients who took the study drug had an average change in pain score of 65, which means that their pain improved. Patients who took the placebo had an average change in pain score of -7, which means that their pain did not improve. The researchers concluded that the difference in these results was not likely due to chance.

The figure on the following page shows the results of the study.



This does not mean that everyone in this study had these results. Other studies may produce different results, as well. 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 PATIENTS HAVE DURING THE STUDY?

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 also have been caused by a study treatment, or by another medicine 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 side effects of a new medicine might be.

One patient left the study due to a medical problem (vomiting), and 15 out of 123 patients in the study had at least 1 non-serious medical problem (that means a medical problem that is not life-threatening, does not cause lasting problems, or does not need hospital care). The most common non-serious medical problems are listed below.

Most Common Non-Serious Medical Problems (Reported by at Least 2% of Patients)

Medical Problem	Ibuprofen 250 mg/ Acetaminophen 500 mg (82 Patients Treated)	Placebo (41 Patients Treated)
Any Medical Problem	11 (13%)	14 (34%)
Nausea	5 (6%)	8 (20%)
Vomiting	4 (5%)	6 (15%)
Dizziness	2 (2%)	4 (10%)
Headache	2 (2%)	4 (10%)

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

A medical problem is considered "serious" when it is life-threatening, causes lasting medical problems, or needs hospital care. No patients in this study had serious medical problems. No patients died during the study.

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. Findings from this study will be used to seek approval for using this new medication to treat pain and fever.

For more details on this study protocol, please visit:

www.clinicaltrials.gov Use the study identifier **NCT02837952**

Please remember that researchers look at the results of many studies to find out which medicines work best and are safest for patients.

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!