



## Clinical Study 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 medication 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:** EUCRISA<sup>®</sup>/STAQUIS<sup>®</sup> (crisaborole)

**Protocol Number:** C3291035

**Dates of Study:** 12 September 2019 to 19 January 2022

**Title of this Study:** Long-Term Use of Crisaborole Ointment Once Daily in Adults, Children, and Infants With Mild-to-Moderate Atopic Dermatitis  
[A Phase 3, Randomized, Double-Blind, Vehicle Controlled Study to Evaluate the Efficacy and Safety of Maintenance Treatment and Flare Reduction with Crisaborole Ointment, 2%, Once Daily Over 52 Weeks in Pediatric and Adult Participants (Ages 3 Months and Older) with Mild-to-Moderate Atopic Dermatitis, who Responded to Twice Daily Crisaborole Ointment, 2%, Treatment]

**Date(s) of this Report:** 06 July 2022

— Thank You —

If you or your child participated in this study, Pfizer, the Sponsor, would like to thank you or your child for your participation.

This summary will describe the study results. If you or your child have any questions about the study or the results, please contact the doctor or staff at your study site.

## Why was this study done?

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### What is atopic dermatitis?

Atopic dermatitis is a common skin condition that can cause many signs and symptoms, such as itching, redness, and a rash that is scaling or oozing. The signs and symptoms can look different on different people. Atopic dermatitis is also known as eczema. People with atopic dermatitis often have this condition for many years, and may have “flare ups”, when their symptoms worsen for a time.

### What is crisaborole?

Crisaborole ointment is sold as EUCRISA<sup>®</sup> in the US and Canada, and as STAQUIS<sup>®</sup> in other countries around the world. It is a phosphodiesterase-4 (PDE4) inhibitor that can inhibit or stop the inflammatory processes in atopic dermatitis. Crisaborole is usually applied to the skin twice a day for treating mild to moderate atopic dermatitis. In this study, crisaborole was applied twice a day or once a day.

### What was the purpose of this study?

The purpose of the study was to see if long-term use of crisaborole ointment applied once a day prevented atopic dermatitis flare ups. To do this, the researchers compared treatment with crisaborole ointment to a vehicle ointment. A vehicle ointment is just like the crisaborole ointment, but it does not contain the active ingredient, crisaborole.

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### Researchers wanted to know:

**Does use of crisaborole ointment once a day delay atopic dermatitis flare ups compared to when participants use vehicle ointment once a day?**

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## What happened during the study?

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### How was the study done?

Researchers tested crisaborole ointment on adults, children and infants aged 3 months or older. They did this to find out if treatment with crisaborole once a day delayed atopic dermatitis flare ups compared to when participants used a vehicle ointment once a day.

Participants went to the study center to be screened by the study doctor to make sure they were able to join the study. This was known as the “screening period” and this lasted up to 4 weeks. In the first part of the study, participants used crisaborole ointment twice a day on the area or areas of skin affected by the atopic dermatitis for up to 8 weeks. This was done to see if the participant’s atopic dermatitis improved with treatment. In this part of the study, the participants knew they were using the crisaborole ointment. This is known as “open label” treatment as everyone knows what treatment is being used.

If the participant’s atopic dermatitis got better, the participant was able to continue in the study. In the next part, participants used either crisaborole ointment or vehicle ointment once a day on the area or areas of skin previously affected by the atopic dermatitis for up to 52 weeks. Treatment was continued providing the participant had no flare ups of atopic dermatitis. In this part of the study, the participants and the researchers did not know who used the crisaborole ointment and who used the vehicle ointment. This is known as “double-blinded” treatment. Participants were assigned to double-blind treatment with crisaborole ointment or vehicle ointment by chance alone. This was done to make sure that the study results were not influenced in any way.

For any participant who had an atopic dermatitis flare up, they were given crisaborole ointment and were to use this twice a day on the affected area of skin for up to 12 weeks. If the participant’s skin cleared or was almost clear, the participant was to go back to using their previously assigned double-blind study medication (either crisaborole ointment or vehicle ointment) once a day.

Researchers then compared the results of participants using crisaborole ointment to the results of participants using vehicle ointment.

### **Where did this study take place?**

The Sponsor ran this study at 42 locations in 6 countries (United States, Australia, Canada, China, Israel, and Turkey).

### **When did this study take place?**

It began 12 September 2019 and ended 19 January 2022.

### **Who participated in this study?**

The study included participants who were aged 3 months or older and who had mild to moderate atopic dermatitis.

- A total of 214 men and boys participated
- A total of 283 women and girls participated
- All participants were between the ages of 5 months and 79 years

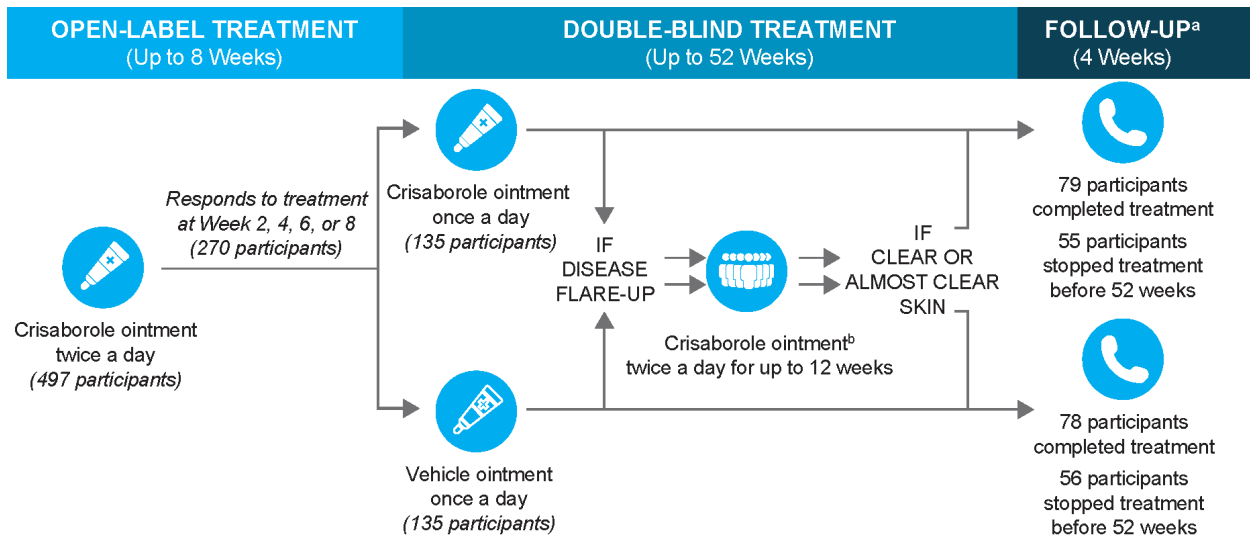
Of the total of 497 participants who started the study and were treated with open label crisaborole ointment twice a day for up to 8 weeks, 270 participants entered the double-blind part of the study.

There were 135 participants who used crisaborole ointment once a day and 135 who used vehicle ointment once a day. Of these, 79 participants who used crisaborole ointment and 78 participants who used vehicle ointment completed up to 52 weeks of treatment.

Most participants who stopped treatment with the study medication (either crisaborole ointment or vehicle ointment) did so because they found the treatment did not work or they decided that they did not want to continue this treatment.

The following figure shows what happened during the study after participants completed the 4-week screening period.

**Figure 1. Study Plan**



a Data was not available for some participants and so the numbers do not add up to the total treated.

b Participants with an atopic dermatitis flare up were to use crisaborole ointment twice a day for up to 12 weeks until their skin was clear or almost clear. After this time, they were to continue with their previous double-blind treatment (either crisaborole ointment or vehicle ointment once a day). Not all participants treated had an atopic dermatitis flare up and there were 167 out of the 270 participants who used open label crisaborole ointment twice a day for a flare up during the study.

## How long did the study last?

Study participants were in the study for about 16 months. The entire study took around 2 years and 4 months to complete.

When the study ended in January 2022, 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?

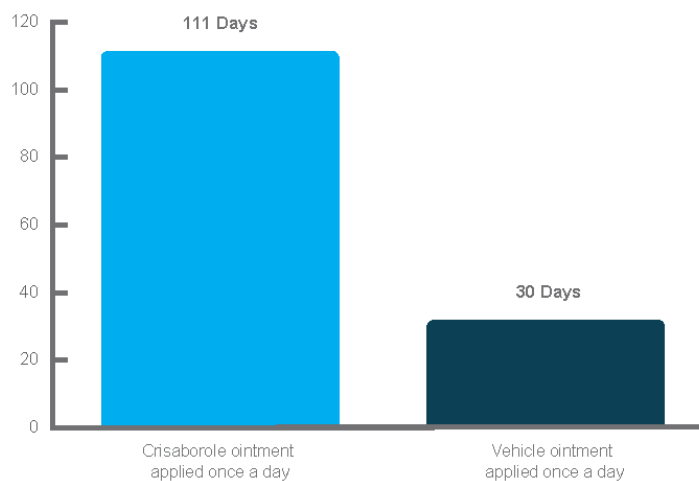
### Does use of crisaborole ointment once a day delay atopic dermatitis flare ups compared to when participants use vehicle ointment once a day?

To answer this question, the researchers looked to see how many days it was before participants had an atopic dermatitis flare up after starting double-blind treatment.

#### How many days did participants go without an atopic dermatitis flare up after starting once daily treatment with crisaborole ointment or vehicle ointment?

Participants who used crisaborole ointment once a day took around 111 days before they had an atopic dermatitis flare up compared with around 30 days for participants who used the vehicle ointment once a day.

**Figure 2. Time in Days Until An Atopic Dermatitis Flare Up**



Based on these results, the researchers have decided that the results are not likely the result of chance. Crisaborole ointment when applied once a day may help delay atopic dermatitis flare ups. These differences could have been due to chance.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies with crisaborole may have different results.

## 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 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 effects a study medication might have on a participant.

At the start of the study when participants were using open label crisaborole twice a day for up to 8 weeks, 109 out of 497 (22%) participants had at least 1 medical problem. These medical problems included pain where they applied the crisaborole ointment (6%), worsening of atopic dermatitis (2%), and a common cold (2%).

During the double-blind treatment period when participants were without atopic dermatitis flares, 85 out of 270 (31%) participants had at least 1 medical problem. The most common medical problems – those reported by 2% or more of participants – are described below.

Below are instructions on how to read Table 1.

### Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by 2% or more of participants are listed.

- The **2nd** column tells how many of the 135 participants using crisaborole ointment once a day reported each medical problem. Next to this number is the percentage who reported the medical problem.
- The **3rd** column tells how many of the 135 participants using vehicle ointment once a day reported each medical problem. Next to this number is the percentage who reported the medical problem.
- Using these instructions, you can see that 0 out of the 135 (0%) participants using crisaborole ointment had an infection of the nose and throat. A total of 5 out of the 135 participants (4%) using vehicle ointment had an infection of the nose and throat.

**Table 1. Commonly reported medical problems during the double-blind treatment period when participants were without atopic dermatitis flare ups**

Medical Problem	Crisaborole Ointment (135 Participants)	Vehicle Ointment (135 Participants)
Infection of the nose and throat	0 out of 135 participants (0%)	5 out of 135 participants (4%)
Common cold	4 out of 135 participants (3%)	2 out of 135 participants (1%)
Infection affecting the large airways in the lungs (bronchitis)	0 out of 135 participants (0%)	3 out of 135 participants (2%)
COVID-19	5 out of 135 participants (4%)	0 out of 135 participants (0%)



**Table 1. Commonly reported medical problems during the double-blind treatment period when participants were without atopic dermatitis flare ups**

<b>Medical Problem</b>	<b>Crisaborole Ointment (135 Participants)</b>	<b>Vehicle Ointment (135 Participants)</b>
<b>Influenza (flu)</b>	3 out of 135 participants (2%)	1 out of 135 participants (1%)
<b>Scratches on skin</b>	3 out of 135 participants (2%)	0 out of 135 participants (0%)
<b>Headache</b>	3 out of 135 participants (2%)	0 out of 135 participants (0%)
<b>Worsening of atopic dermatitis</b>	0 out of 135 participants (0%)	3 out of 135 participants (2%)

There were 167 participants who had atopic dermatitis flare ups and used open label crisaborole twice a day for up to 12 weeks during this study. Of these, 37 (22%) participants had at least 1 medical problem. These medical problems included an infection where they applied the crisaborole ointment (2%) and worsening of atopic dermatitis (2%).

Some participants stopped using the study ointment because of medical problems:

- Twenty-six (26) out of 497 (5%) participants stopped using open label crisaborole twice a day at the start of the study
- One (1) out of 135 (1%) participants using crisaborole once a day and 3 out of 135 (2%) participants using vehicle ointment once a day stopped using their study ointment during the double-blind treatment period when participants were without atopic dermatitis flare ups

- Three (3) out of 167 (2%) participants who had an atopic dermatitis flare up and used open label crisaborole twice a day for up to 12 weeks stopped using this ointment

The researchers thought that the medical problems seen in this study were similar to the known safety profile of crisaborole.

## Did study participants have any serious medical problems?

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

Serious medical problems were reported for:

- Three (3) out of 497 participants (1%) who were using open label crisaborole twice a day at the start of the study
- Two (2) out of 135 (1%) participants using crisaborole once a day and 3 out of 135 (2%) participants using vehicle ointment once a day during the double-blind treatment period when participants were without atopic dermatitis flare ups
- Two (2) out of 167 (1%) participants who had an atopic dermatitis flare up and used open label crisaborole twice a day for up to 12 weeks

Only 1 of these participants had serious medical problems that the study doctor thought were related to treatment. This was a participant who was using open label crisaborole twice a day at the start of the study and who had a worsening of their atopic dermatitis, a skin infection, and an infection where the ointment was applied.

No participants died during the study.



## Where can I learn more about this study?

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

For more details on your study protocol, please visit:

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)  
[www.pfizer.com/research/  
research\\_clinical\\_trials/trial\\_results](http://www.pfizer.com/research/research_clinical_trials/trial_results)

Use the study identifier NCT04040192  
Use the protocol number C3291035

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

Again, if you or your child participated in  
this study, **thank you** for volunteering.  
We do research to try to find the  
best ways to help patients, and you helped  
us to do that!