BREATHE

Ifetroban for Aspirin Exacerbated Respiratory Disease

What will happen in the BREATHE study?

Screening

Up to 2 weeks

- Check whether you are eligible for the study

Treatment Period

Up to 8 weeks

- You will take the study drug once every day
- You will be given a study diary to record your symptoms, respiratory reactions, sinus infections and medications taken
- You will visit the study center twice
- The study doctor will notify you when to stop treatment and return for your follow-up visit

Follow-up Period

2 weeks after the end-of-treatment visit

- Check how you are feeling after stopping the study drug

At the study visits a variety of assessments will be done, including:

- physicial exam and check vital signs
- breathing, smell and lung function tests
- blood and urine tests
- answer questions about your sino-nasal symptoms and quality of life

What else do I need to consider?

The study drug, assessments and medical care related to the study will be provided at no cost to you.

Like many medications, ifetroban may cause side effects. The study doctor will review possible side effects with you.

Ifetroban may improve your AERD symptoms, however this is not guaranteed. The study team will be able to explain fully the potential risks and benefits of joining this study.

Even if there is no direct benefit to you, the data collected from this study may help us learn more about ifetroban and AERD.

What do I do now?

To learn more about the BREATHE Study, please speak to your doctor or contact the study team using the details below:

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AERD CLINICAL TRIAL

PATIENT INFORMATION

If you are an adult with symptomatic AERD, you may be eligible to take part in a clinical research study called, BREATHE.

About Clinical Research Studies

All medications must be tested in a series of clinical research studies, also called clinical trials, before they can be approved and prescribed by doctors. Some clinical research studies are designed to look at the safety and/or effectiveness of potential new medications, and some clinical research studies are designed to collect additional information about medications that are already approved. Without these clinical research studies, few medical advances would be made.

Choosing to take part in a clinical research study is an important personal decision for you. This brochure contains information that may help you decide whether you would like to take part in the BREATHE Study.

What is AERD & how is it treated?

Aspirin Exacerbated Respiratory Disease (AERD) is a chronic medical condition that consists of asthma, recurrent sinus disease with nasal polyps, and a sensitivity to aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs). While there is no known cure for AERD, chronic high-dose aspirin therapy is sometimes effective at controlling symptoms.

About the BREATHE Study

Ifetroban is an investigational drug, meaning that it is not approved by the United States Food and Drug Administration (FDA). The FDA allows this drug to be used only in research. Ifetroban has been studied in 26 clinical studies in over 1,300 people. These studies have included healthy volunteers, patients with various cardiovascular diseases, patients with liver and kidney disease, and one study in patients with AERD. The purpose of this study is to find out if ifetroban will improve the sino-nasal symptoms and quality-of-life of patients with symptomatic AERD.

Approximately 76 people will take part in the BREATHE Study. Half of the participants in this study will receive ifetroban and half will receive placebo. During the study, treatment will be unknown to participants, their doctor, the research team and the study sponsor.

Participants who volunteer to take part in the BREATHE Study will have 4-5 study visits 2-4 weeks apart. Treatment is taken for 8 weeks followed by a 2-week follow-up period.

About Ifetroban

Ifetroban belongs to a group of medicines called thromboxane receptor antagonists. In animal studies, ifetroban prevented symptoms associated with a respiratory reaction. Ifetroban is taken as a capsule.

Who can take part in the BREATHE Study?

You may be eligible to join the study if:

- ✔ You are 18 years of age or older
- ✔ You have been diagnosed with AERD
- ✔ You have stable asthma
- ✔ You have sino-nasal symptoms

You also **must not**:

- X Be a current smoker
- X Be pregnant or breastfeeding
- X Be using steroids > 20 mg per day
- X Be taking NSAIDs
- X Have a history of a bleeding condition
- X Be using an antiplatelet agent

The study doctor will evaluate your eligibility and let you know if you are a candidate for participation.