

Developing DUEXIS

For people with osteoarthritis and rheumatoid arthritis, gastroprotection can be just as important as symptom relief.

By combining the benefits of an NSAID and a medicine to decrease the risk of developing NSAID-induced stomach ulcers in one pill, the risk of patient non-compliance for gastroprotection is reduced.



DUEXIS was approved by the U.S. FDA based on a rigorous development program



2 randomized Phase 3 clinical trials for DUEXIS



1,500+ DUEXIS study participants

DUEXIS® (ibuprofen and famotidine) tablets

- DUEXIS contains two medicines: **ibuprofen**, a nonsteroidal anti-inflammatory drug (NSAID) and **famotidine**, a histamine H₂ receptor blocker medicine that acts as a gastroprotective agent
- In clinical trials, DUEXIS was shown to reduce the risk of developing stomach ulcers associated with ibuprofen use by about 50%
- The clinical trials primarily enrolled patients less than 65 years of age without a prior history of stomach ulcer

A Major Health Risk



As many as one in four regular NSAID users can develop a stomach ulcer. Most people may never feel the stomach ulcer developing—but stomach ulcers can be very dangerous and lead to serious health complications.



25% of physicians co-prescribe an NSAID and an agent to reduce the risk of developing NSAID-related stomach ulcers.



Less than 40% of the few patients who are co-prescribed an NSAID are still taking the gastroprotective agent after three NSAID prescriptions.

SELECTED IMPORTANT SAFETY INFORMATION

DUEXIS is a prescription medicine used to relieve the signs and symptoms of rheumatoid arthritis and osteoarthritis, and to decrease the risk of developing ulcers of the stomach and upper intestines (upper gastrointestinal ulcers) in people taking ibuprofen for rheumatoid arthritis and osteoarthritis.

Please see page 3 or [click here](#) for the full prescribing information including Boxed Warning.

What is the most important information I should know about DUEXIS?

- DUEXIS can cause an increased risk of a heart attack or stroke that can lead to death. This risk may occur early in treatment and may increase with longer use and with increasing doses of medicine containing NSAIDs.
- DUEXIS can cause an increased risk of bleeding, ulcers, and tears (perforations) of the esophagus, stomach, and intestines. These events can occur at any time during use, without warning symptoms, and may cause death. Elderly patients and patients with a history of ulcer disease or stomach or intestinal bleeding are at greater risk for getting an ulcer or bleeding.
- You should take DUEXIS exactly as prescribed, at the lowest dose possible and for the shortest time needed.

✘ **MYTH**

DUEXIS is simply a combination of cheaper, over-the-counter medicines.

✔ **FACT**

There are no approved generic or over-the-counter products that have been deemed pharmaceutical or therapeutic equivalent medicines to DUEXIS. The FDA prescribing information specifically states, **“do not substitute DUEXIS with the single-ingredient products of ibuprofen and famotidine.”**

✘ **MYTH**

NSAID-induced GI toxicity is not a major health risk.

✔ **FACT**

NSAIDs can put you at risk for stomach ulcers — sores on the lining of your stomach caused by stomach acid.

✘ **MYTH**

DUEXIS did not require any research and development, it is just a combination of two medicines.

✔ **FACT**

Horizon invested significantly into two randomized Phase 3 clinical trials involving over 1,500 patients in order to secure FDA approval.

✘ **MYTH**

Patients pay the list price

✔ **FACT**

The out-of-pocket cost for DUEXIS for 98 percent of all commercially insured patients is \$25 or less.

The list price is not what patients pay for the medicine. It does not reflect many factors including the patient support that Horizon provides, rebates to the health plans and pharmacy benefit managers, as well as discounts and processing fees charged by managed care providers.

✘ **MYTH**

DUEXIS adds significant cost to the health system.

✔ **FACT**

DUEXIS represents less than one percent of NSAID use.

INDICATIONS AND USAGE FOR DUEXIS®

What is DUEXIS® (ibuprofen and famotidine)?

DUEXIS contains two medicines: ibuprofen, a nonsteroidal anti-inflammatory drug (NSAID), and famotidine, a histamine H₂-receptor blocker medicine.

DUEXIS is a prescription medicine used to:

- relieve the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- decrease the risk of developing ulcers of the stomach and upper intestines (upper gastrointestinal ulcers) in people taking ibuprofen for rheumatoid arthritis and osteoarthritis.

It is not known if DUEXIS is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about DUEXIS?

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- DUEXIS can cause an increased risk of bleeding, ulcers, and tears (perforation) of the esophagus, stomach and intestines. These events can occur at any time during use, without warning symptoms and may cause death. Elderly patients and patients with a history of ulcer disease or stomach or intestine bleeding are at greater risk for getting an ulcer or bleeding.
- You should take DUEXIS exactly as prescribed, at the lowest dose possible and for the shortest time needed.

DUEXIS can cause serious side effects. Stop taking DUEXIS and call your doctor or go to your emergency department right away if you get:

- Difficulty breathing, swelling of the face or throat. These could be signs of a serious allergic reaction.
- Chest pain, shortness of breath, weakness in one part or side of your body, or slurring of speech. These could be signs of a serious blood clotting event.
- Upper stomach pain, upset stomach, black, tarry stools, or vomiting of blood. These could be signs of an esophagus, stomach, or intestinal ulcer, bleed, or tear. Note: if you are also taking low-dose aspirin, you are at increased risk for esophagus, stomach, or intestinal bleeding.
- Nausea, more tired or weaker than usual, itching, yellowing of the skin or eyes, right upper abdomen tenderness, and "flu-like" symptoms. These could be signs of a liver problem.
- Shortness of breath, unexplained weight gain, or swelling of the arms, legs, hands or feet. These could be signs of a serious heart problem.
- Any type of rash. This could be a sign of a serious skin reaction.

These are not all of the possible side effects of DUEXIS. Please talk to your doctor if you experience any symptoms that bother you or that do not go away. If you take too much DUEXIS, call your poison control center at 1-800-222-1222.

Who should not use DUEXIS?

Do not take DUEXIS:

- if you are allergic to ibuprofen, famotidine, any other histamine H₂-receptor blocker, or any of the ingredients in DUEXIS. See the Medication Guide for a complete list of ingredients.
- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- right before or after heart bypass surgery called coronary artery bypass graft.

How should I take DUEXIS?

Take DUEXIS exactly as your health care provider tells you to take it. Do not change your dose or stop DUEXIS without first talking to your health care provider. Swallow DUEXIS tablets whole with liquid. Do not split, chew, crush, or dissolve the DUEXIS tablet. If you forget to take a dose of DUEXIS, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose. Take the next dose on time. Do not take 2 doses at one time to make up for a missed dose. You should not take an ibuprofen tablet and famotidine tablet together instead of taking a DUEXIS tablet, because they will not work in the same way.

What are the possible side effects of DUEXIS?

The most common side effects of DUEXIS include nausea, diarrhea, constipation, upper abdominal pain, and headache.

What other medications might interact with DUEXIS?

Do not use DUEXIS while taking other NSAIDs unless your health care provider says it is OK. NSAIDs may be present in over-the-counter medications for treatment of colds, fever, or insomnia; refer to the label of over-the-counter medications you are taking or ask your pharmacist. Do not use DUEXIS and low-dose aspirin until you talk to your health care provider. Tell your health care provider about all of the medicines you take as some medicines can react with NSAIDs and cause serious side effects.

What should I tell my health care provider?

Before starting DUEXIS, tell your health care provider if you have a history of ulcer disease or esophagus, stomach, or intestine bleeding, liver or kidney problems, high blood pressure, heart problems, bleeding problems, asthma, or are pregnant, trying to become pregnant, or breast feeding. Also tell your health care provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins, or herbal supplements. Do not start taking new medicines without talking to your health care provider first.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. You may also contact the Horizon Medical Information Department toll-free at 1-866-479-6742 or medicalinformation@horizontherapeutics.com.

The risk information provided here is not comprehensive. To learn more, talk about DUEXIS with your health care provider or pharmacist. The FDA-approved product labeling can be found at www.DUEXIS.com or 1-866-479-6742.