

Medication Guide for Nonsteroidal Anti-inflammatory Drugs (NSAIDs) and DUEXIS

What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

NSAIDs can cause serious side effects including:

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:
 - with increasing doses of NSAIDs
 - with longer use of NSAIDs

Do not take NSAIDs right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

Avoid taking NSAIDs after a recent heart attack, unless your health care provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

- **Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:**
 - anytime during use
 - without warning symptoms
 - that may cause death

The risk of getting an ulcer or bleeding increases with:

- past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”
- increasing doses of NSAIDs
- longer use of NSAIDs
- smoking
- drinking alcohol
- older age
- poor health
- advanced liver disease
- bleeding problems

NSAIDs should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

What are NSAIDs?

NSAIDs are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as different types of arthritis, menstrual cramps, and other types of short-term pain.

Who should not take NSAIDs?

Do not take NSAIDs:

- 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.

Before taking NSAIDs, tell your health care provider about all of your medical conditions, including if you:

- have liver or kidney problems
- have high blood pressure
- have asthma
- are pregnant or plan to become pregnant. Talk to your health care provider if you are considering taking NSAIDs during pregnancy. **You should not take NSAIDs after 29 weeks of pregnancy.**
- are breastfeeding or plan to breast feed.

Tell your health care provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements. NSAIDs and some other medicines can interact with each other and cause serious side effects. **Do not start taking new medicine without talking to your health care provider first.**

What are the possible side effects of NSAIDs?

NSAIDs can cause serious side effects, including:

See “What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- **Other side effects of NSAIDs include:** stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness

Get emergency help right away if you get any of the following symptoms:

- shortness of breath
- chest pain
- slurred speech
- swelling of the face or throat

- weakness in one part or side of your body

Stop taking your NSAID and call your health care provider right away if you get any of the following symptoms:

- | | |
|-----------------------------------|--|
| • nausea | • vomit blood |
| • more tired or weaker than usual | • there is blood in your bowel movement or it is black and sticky like tar |
| • diarrhea | • unusual weight gain |
| • itching | • skin rash or blisters with fever |
| • your skin or eyes look yellow | • swelling of the arms, legs, hands, and feet |
| • indigestion or stomach pain | |
| • flu-like symptoms | |

If you take too much of your NSAID, call your health care provider or get medical help right away.

These are not all the possible side effects of NSAIDs. For more information, ask your health care provider or pharmacist about NSAIDs.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Other information about NSAIDs

- Aspirin is an NSAID but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some NSAIDs are sold in lower doses without a prescription (over-the-counter). Talk to your health care provider before using over-the-counter NSAIDs for more than 10 days.

What is DUEXIS?

DUEXIS contains two medicines:

1. Ibuprofen is a nonsteroidal anti-inflammatory drug (NSAID). Please read the above information regarding the benefits and risks of NSAIDs, including ibuprofen, a component of DUEXIS.
2. Famotidine is a histamine 2 (H2)-receptor antagonist, a medicine that may help reduce stomach acid.

DUEXIS is a prescription medicine used to:

- relieve 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 who are taking ibuprofen for rheumatoid arthritis and osteoarthritis. DUEXIS was studied mostly in people less than 65 years of age and who did not have a prior history of ulcers of the stomach and upper intestines.

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

Other information about DUEXIS (ibuprofen and famotidine)

- Ibuprofen may cause meningitis, a serious brain problem. Call your health care provider if you have any of the following symptoms of meningitis:

○ headache	○ unusual sensitivity to light
○ fever	○ muscle pain
○ nausea	○ chills
○ vomiting	○ confusion
○ stiff neck	○ drowsiness
○ rash	
- Tell your health care provider if you develop blurred or decreased vision, changes in color vision, or any other problems with your eyes

How should I take DUEXIS?

- Take DUEXIS exactly as your health care provider tells you to take it.
- Your health care provider will tell you how many DUEXIS to take and when to take them.
- 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. Tell your health care provider if you cannot swallow the tablet whole. You may need a different medicine.
- 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.

General information about the safe and effective use of NSAIDs

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NSAIDs for a condition for which it was not prescribed. Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about NSAIDs, talk with your provider. You can ask your pharmacist or health care provider for information about NSAIDs that is written for health care professionals.

Distributed by: Horizon Pharma USA Inc., Lake Forest, IL 60045

For more information, go to www.DUEXIS.com or call 1-866-479-6742.

This Medication Guide has been approved by the U.S. Food and Drug Administration

Revised May 2016