

Updated NSAID warnings: help your patients understand risks

The U.S. Food and Drug Administration (FDA) required an update to the Drug Facts labeling of all adult and pediatric **non-aspirin OTC nonsteroidal anti-inflammatory drugs (NSAIDs)**, for example, Motrin®, Advil®, and Aleve® products. These changes strengthen and expand existing warnings relating to the risk of heart attack and stroke associated with NSAIDs.

The chart below shows the differences between the previous label and the updated label in the Warnings section. Ask your healthcare professional if you have questions about the warnings.

Previous NSAID Warnings

Do not use

- right before or after heart surgery

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- you are taking a diuretic

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

Updated NSAID Warnings

The following warning was added under the Warnings section of the labeling



Heart attack and stroke warning
NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or **had a stroke**
- you are taking a diuretic



When using this product

- take with food or milk if stomach upset occurs
- **the risk of heart attack or stroke may increase if you use more than directed or for longer than directed**



Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- **you have symptoms of heart problems or stroke:**
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

