

LEADER DUAL ACTION PAIN RELIEVER- acetaminophen, ibuprofen tablet, film coated

Cardinal Health 110, LLC. dba Leader

Cardinal Health Dual Action Pain Reliever Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg

Ibuprofen 125 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - toothache
 - backache
 - menstrual cramps
 - muscular aches
 - minor pain of arthritis

Warnings

Acetaminophen liver damage warning:

This product contains acetaminophen. Severe liver damage may occur if you take:

- with other drugs containing acetaminophen
- more than 6 caplets in 24 hours, which is the maximum daily amount for this product
- 3 or more alcoholic drinks every day while using this product

Acetaminophen allergy alert: may cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away.

NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

NSAID stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

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.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- if you have ever had an allergic reaction to acetaminophen or any other pain reliever
- right before or after heart surgery

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers
- 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

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

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
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed**

Adults and children 12 years and over: take 2 caplets every 8 hours while symptoms persist

Children under 12 years: ask a doctor

Other information

- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, ferric oxide yellow, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

LEADER_{TM}

Dual Action Pain Reliever

Acetaminophen 250 mg and Ibuprofen (NSAID) 125 mg Tablets

Pain Reliever

CONTAINS 2 MEDICINES

Acetaminophen + Ibuprofen

COMPARE TO ADVIL[®] DUAL ACTION active ingredients

36 CAPLETS**

**Capsule-Shaped Tablets

ACTUAL SIZE

100% Money Back Guarantee



Do not use with other medicines containing ACETAMINOPHEN; can cause liver damage.

Drug Facts

Active ingredients (in each capsule)	Purposes
Acetaminophen 250 mg.....	Pain reliever
Ibuprofen 125 mg (NSAD)*.....	Pain reliever
No steroidal anti-inflammatory drug	

Pain relief

Uses ■ temporarily relieves minor aches and pains due to: ■ headache ■ toothache ■ backache ■ menstrual cramps ■ muscular aches ■ minor pain of arthritis

Warnings

Acetaminophen liver damage warning:

damage may occur if you take ☐ with other drugs containing acetaminophen ☐ more than 6 capsules in 24 hours, which is the maximum daily amount for this product ☐ 3 or more alcoholic drinks every day while using this product.

Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash ■ skin reaction occurs, stop use and seek medical help right away.

NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Drug Facts (continued)

Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ skin redness ■ rash ■ blisters
If an allergic reaction occurs, stop use and seek medical help right away.

NSAID stomach bleeding warning.
This product contains an NSAID, which may increase the risk of stomach bleeding.

the product. ■ take more or for a longer time than directed

Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ if you have ever had an allergic reaction to acetaminophen or any other pain reliever. ■ right before or after heart surgery.

Ask a doctor or health care provider if you have liver disease, stomach bleeding, or serious side effects from taking pain relievers. 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.

Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any serious condition ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin ■ taking any other drug

Do not use if printed seal under cap is broken or missing.

CIN 5990783 REV. 06/25



53J68 E9 C1

Drug Facts (continued)

When using this product
 ■ take with food or milk if stomach upset occurs

Stop use and ask a doctor if ■ you experience any of the following signs of stomach bleeding:

☐ feel full ☐ 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 ☐ redness or swelling is present in the painful area ☐ any new symptom appears

IV days ☐ redness or swelling is present
painful area ☐ any new symptoms appear

If your infant or breast-feeding baby has a health professional before you, it's especially important not to use ibuprofen at 20 weeks or later in pregnancy unless you've been specifically advised to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get help or treat if needed. Call a Poison Center. Don't Gasteright Adult (1-800-222-4322). Prompt medical attention is critical for signs as well as for children even if you do not notice any signs or symptoms.

Directions ■ do not take more than an affected Adult and children 12 years and over: take 2 capsules every 8 hours while symptoms persist. Children under 12 years: ask a doctor ■ do not take more than 6 capsules in 24 hours, unless directed by a doctor ▼

Drug Facts (continued)

Other information

Read all warnings and instructions before use.
Keep cool. Store at 20–25°C (68–77°F).
Avoid excessive heat above 40°C (104°F).

Inactivated vaccines contain killed or non-diseased organisms, or components of organisms, such as proteins, polysaccharides, or toxins. They are prepared by growing the organisms in a suitable medium, then killing them with heat or chemicals, or by extracting specific components. Examples include:

Questions or comments? 1-800-719-9260

The product is not an emulsion but is distributed by BSK
 Our new Health care distributor of Advant® Dual Action,
 CRYSTAL RESEARCH & CRYSTAL HEALTH, 0.001 IN. OIL/0.010
 IN. WATER/RESEARCH 1-800-2-00-5355

LEADER²™

NDC 70000-0737-2

Dual Action Pain Reliever

**Acetaminophen 250 mg and
Ibuprofen (NSAID) 125 mg Tablets**
Pain Reliever

CONTAINS 2 MEDICINES
Acetaminophen + Ibuprofen

36 CAPLETS**
**Capsule-Shaped Tablets



**COMPARE TO
ADVIL® DUAL ACTION**
active ingredients†

100% Money Back Guarantee

LEADER DUAL ACTION PAIN RELIEVER

acetaminophen, ibuprofen tablet, film coated

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0737
Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)			ACETAMINOPHEN	250 mg
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)			IBUPROFEN	125 mg
Inactive Ingredients				
Ingredient Name				Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	YELLOW	Score	no score	
Shape	OVAL	Size	14mm	
Flavor		Imprint Code	II	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0737-2	1 in 1 CARTON	09/30/2025	
1		36 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0737-1	1 in 1 CARTON	09/30/2025	
2		18 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214836	09/30/2025	

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 9/2025

Cardinal Health 110, LLC. dba Leader