

BACK AND BODY EXTRA STRENGTH- aspirin, caffeine tablet, film coated
Cardinal Health 110, LLC. DBA Leader

Leader 44-413

Active ingredients (in each caplet)

Aspirin 500 mg (NSAID)*

Caffeine 32.5 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Pain reliever aid

Uses

for the temporary relief of

- backache pain
- muscle aches and pains
- minor aches and pains of arthritis

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- shock
- facial swelling
- asthma (wheezing)

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

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

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have asthma
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- gout
- diabetes
- arthritis

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - vomit blood
 - have bloody or black stools
 - feel faint
 - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin 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.

Directions

- **do not take more than directed**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours, not to exceed 8 caplets in 24 hours
- children under 12 years: do not use unless directed by a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, sodium lauryl sulfate

Questions or comments?

1-800-426-9391

Principal display panel

LEADER™

NDC 70000-0127-2

**Extra Strength
Back & Body
Aspirin (NSAID), 500 mg | Caffeine, 32.5 mg
Pain Reliever | Pain Reliever Aid**

Relieves Backaches
and Muscle Aches & Pains

**COMPARE TO
BAYER® BACK & BODY**
active ingredients†

100% Money Back Guarantee

100 CAPLETS

Actual Size

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

†This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer® Back & Body.

50844 REV0222B41312

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no print / no varnish area
lot no. & exp. date

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CIN 5285796 REV. 4/22

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

NDC 70000-0127-2

LEADER

Extra Strength

Back & Body

Aspirin (NSAID), 500 mg | Caffeine, 32.5 mg
Pain Reliever | Pain Reliever Aid

Relieves Backaches and Muscle Aches & Pains

100 CAPLETS Actual Size

COMPARE TO BAYER® BACK & BODY active ingredients*

100% Money Back Guarantee

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Drug Facts (continued)

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Drug Facts (continued)

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1-800-426-6391

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Leader 44-413

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

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BACK AND BODY EXTRA STRENGTH

aspirin, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0127
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32.5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	44;413
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0127-2	1 in 1 CARTON	04/12/2004	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:70000-0127-1	1 in 1 CARTON	04/12/2004	08/08/2021
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	04/12/2004	

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0127)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0127)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0127)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0127)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0127)

Revised: 5/2025

Cardinal Health 110, LLC. DBA Leader