

## **BACK AND BODY EXTRA STRENGTH- aspirin, caffeine tablet, film coated** **Cardinal Health**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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

**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
- take more or for a longer time than directed
- 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
- have had stomach ulcers or bleeding problems

### **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 high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- 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:
  - feel faint
  - have bloody or black stools
  - vomit blood
  - 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 during the last 3 months of 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**

- 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 REV0818A41312

**CardinalHealth™**

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

**Essential to Care™ since 1979**

**100% Money Back Guarantee**  
Return to place of purchase if not satisfied.

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CIN 5285796

REV. 2/21

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**Drug Facts (continued)**

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**KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

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# BACK AND BODY EXTRA STRENGTH

aspirin, caffeine tablet, film coated

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0127-1	1 in 1 CARTON	04/12/2004	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:70000-0127-2	1 in 1 CARTON	04/12/2004	
2		100 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
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OTC monograph not final	part343	04/12/2004	
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**Labeler** - Cardinal Health (097537435)

### Establishment

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

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(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.		868734088	pack(70000-0127)

Revised: 3/2021

Cardinal Health