# EXTRA STRENGTH BACK AND BODY- as pirin and caffeine capsule WALGREEN CO.

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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## Walgreens 44-413

## Active ingredients (in each caplet)

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

- have had stomach ulcers or bleeding problems, are age 60 or older
- take a blood thinning (anticoagulant) or steroid drug
- take other 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

#### Do not use

• if you are allergic to aspirin or any other pain reliever/fever reducer

#### 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, lover 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

- 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
- an allergic reaction occurs. Seek medical help right away.
- new symptoms occur
- ringing in the ears or 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

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 hour
- children under 12 years: do not use unless directed by a doctor

#### Other information

- store at controlled room temperature 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

Well at

Walgreens

WALGREENS PHARMACIST RECOMMENDED

NDC 0363-0431-15

EXTRA STRENGTH

Back & Body

Aspirin (NSAID) /

Caffeine / Pain Reliever Aid

• Fast relief at the site of pain

**50** 

**COATED CAPLETS** 

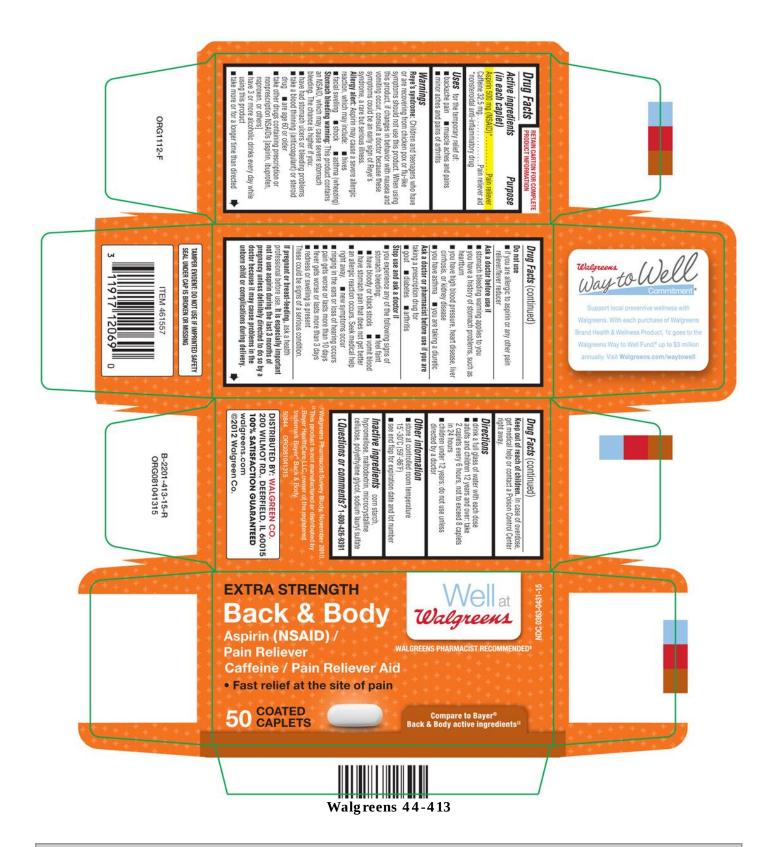
Compare to Bayer® Back & Body active ingredients

Walgreens Pharmacist Survey Study, November 2010.

IIIThis product is not manufactured or distributed by Bayer HealthCare, LLC, owner of the registered trademark Bayer® Back & Body.

50844 ORG081041315

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



#### EXTRA STRENGTH BACK AND BODY

aspirin, caffeine capsule

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0363-0431
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ASPIRIN (ASPIRIN)	ASPIRIN	500 mg	
CAFFEINE (CAFFEINE)	CAFFEINE	32.5 mg	

Inactive Ingredients	
Ingredient Name	Strength
SODIUM LAURYL SULFATE	

Product Characteristics			
Color	WHITE	Score	no score
Shape	CAPSULE	Size	19 mm
Flavor		Imprint Code	44;413
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0431-15	1 in 1 CARTON		
1		50 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	04/12/2004	

## Labeler - WALGREEN CO. (008965063)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0431)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	MANUFACTURE(0363-0431)	

Revised: 3/2013 WALGREEN CO.