

BACK AND BODY EXTRA STRENGTH- aspirin, caffeine tablet, film coated
GREENBRIER INTERNATIONAL, INC.

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.

Assured 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
- 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

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 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 (1-800-222-1222) 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 or 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

ASSURED™

**COMPARE TO ACTIVE INGREDIENTS OF
BAYER® Back & Body†**

EXTRA STRENGTH

Back & Body

• Aspirin (NSAID) & Caffeine

Pain Reliever / Pain reliever aid

Actual Size

24 coated caplets

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

†This product is not manufactured or distributed by Bayer
HealthCare LLC, owner of the registered trademark Bayer®
Back & Body. 50844 REV0818D41308

ITEM# 125702

Distributed by: **Greenbrier International, Inc.**
Chesapeake, VA 23320 USA

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SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



B-0316-413-08-R
REV0818D41308



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Drug Facts (continued)

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Drug Facts (continued)

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44-413

BACK AND BODY EXTRA STRENGTH

aspirin, caffeine tablet, film coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:33992-0413

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

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:33992-0413-8	1 in 1 CARTON	04/12/2004	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:33992-0413-2	1 in 1 CARTON	04/12/2004	03/29/2019
2		48 in 1 BOTTLE; Type 0: Not a Combination Product		

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

Labeler - GREENBRIER INTERNATIONAL, INC. (610322518)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(33992-0413)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(33992-0413)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(33992-0413)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(33992-0413)

Revised: 2/2020

GREENBRIER INTERNATIONAL, INC.