BACK AND BODY EXTRA STRENGTH- aspirin, caffeine tablet
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 and 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.

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

- you experience any of the following signs of stomach bleeding:
  - have bloody or black stools
  - vomit blood
  - feel faint
  - 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 (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 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- 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

†This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Back & Body.
50844 REV0113C41308

ITEM# 125702
Distributed by: **Greenbrier International, Inc.**
Chesapeake, VA 23320 USA

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

Assured 44-413

BACK AND BODY EXTRA STRENGTH

aspirin, caffeine tablet

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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	44;413
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0413-2	1 in 1 CARTON		
1		48 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:33992-0413-8	1 in 1 CARTON		
2		24 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)