HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin and caffeine tablet, film coated
CHAIN DRUG MARKETING ASSOCIATION INC

Quality Choice 44-159B

Active ingredients (in each tablet)

Acetaminophen 250 mg
Aspirin 250 mg (NSAID)*
Caffeine 65 mg
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever
Pain reliever
Pain reliever aid

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - toothache
  - muscular aches
  - premenstrual and menstrual cramps

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)

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if

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

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug or are under a doctor's care for any serious condition

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
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

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 accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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 tablets every 6 hours. Do not take more than 8 tablets in 24 hours.
- children under 12 years: ask 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, crospovidone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

NDC 63868-485-01

QC®
QUALITY
CHOICE

Compare to the active ingredients in EXCEDRIN® EXTRA STRENGTH†

Headache Relief Extra Strength
Acetaminophen, Aspirin **(NSAID)** and Caffeine
Pain Reliever | Pain Reliever Aid

100 Coated Tablets

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 GSK Consumer Healthcare SARL, owner of the registered trademark Excedrin® Extra Strength. 50844 REV1121G15912

SATISFACTION 100% QC GUARANTEED

Distributed by CDMA, Inc.
43157 W Nine Mile
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

Quality Choice 44-159B

HEADACHE RELIEF EXTRA STRENGTH

acetaminophen, aspirin and caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-485
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	44;159
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-485-24	1 in 1 CARTON	11/17/1992	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63868-485-50	1 in 1 CARTON	11/17/1992	
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:63868-485-01	1 in 1 CARTON	11/17/1992	
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:63868-485-02	1 in 1 CARTON	11/17/1992	06/15/2019
4		200 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	11/17/1992	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(63868-485)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(63868-485)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(63868-485)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(63868-485)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(63868-485)

Revised: 7/2023 CHAIN DRUG MARKETING ASSOCIATION INC