

HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin and caffeine tablet, film coated
GREAT LAKES WHOLESAL, MARKETING, & SALES, 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.

Healthcare 44-159B Delisted

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:
 - toothache
 - arthritis
 - a cold
 - headache
 - 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
- shock
- facial swelling
- 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

- are age 60 or older
- 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
- take more or for a longer time than directed

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 liver disease
- stomach bleeding warning applies to you
- 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
- you have asthma

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
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for 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 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°C-30°C (59°F-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?

Call 1-800-426-9391

Principal Display Panel

HEALTHCARE™

NDC 64092-112-50

†Compare to the
active ingredients in
Excedrin® Extra Strength

EXTRA STRENGTH

Headache Relief

Acetaminophen, Aspirin (NSAID) and Caffeine
Pain Reliever, Pain Reliever Aid

For Pain of Headaches, Arthritis and Muscular Aches

Actual size

50 TABLETS

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

HEALTHCARE GUARANTEE

**If you are not completely satisfied with this
product, regardless of reason, return your unused
portion to Great Lakes Wholesale for a full refund**

†This product is not manufactured or distributed by GSK Consumer
Healthcare S.A., owner of the registered trademark Excedrin® Extra
Strength. 50844 REV1119L15915

Distributed by: Great Lakes Wholesale & Marketing L.L.C.
3729 Patterson Ave., S.E., Grand Rapids, MI 49512
www.glwholesale.com

No print/No varnish
Lot & Exp date

7 92215 80112 0

This product is not manufactured or distributed by SSK Consumer Healthcare S.A., owner of the registered trademark Exceldrin Extra Strength 50/64. RCV1191L15915
Distributed by: Great Lakes Wholesale & Marketing, L.L.C.
3729 Patterson Ave., S.E., Grand Rapids, MI 49512
www.glwholesale.com

HEALTHCARE™

EXTRA STRENGTH

Headache Relief

Acetaminophen, Aspirin (NSAID) and Caffeine
Pain Reliever, Pain Reliever Aid

For Pain of Headaches, Arthritis and Muscular Aches

NDC 64092-112-50
Compare to the active ingredients in Exceldrin® Extra Strength

Actual size



50 TABLETS

HEALTHCARE GUARANTEE
If you are completely satisfied with the product, we will refund the purchase price. If you are not completely satisfied, we will refund the purchase price for a full refund.

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

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Inactive ingredients: corn starch, croscollon, hydroxypropyl methylcellulose, polydome, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Drug Facts (continued)
See end flap for expiration date and lot number

B-0616-1598-15
RCV1191L15915

Drug Facts (continued)

Take any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if:

- you experience any of the following signs of stomach bleeding:
 - have bloody or black stools
 - have stomach pain that does not get better
 - ringing in the ears or a loss of hearing occurs
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- These could be signs of a serious condition.
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No Print
Glue Area

No Print
Glue Area

Drug Facts (continued)

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Glue Area

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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Healthcare 44-159B

HEADACHE RELIEF EXTRA STRENGTH acetaminophen, aspirin and caffeine tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-112
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)	
CROSPVIDONE, 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:64092-112-50	1 in 1 CARTON	11/17/1992	10/24/2024
1		50 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 not final	part343	11/17/1992	10/24/2024

Labeler - GREAT LAKES WHOLESALE, MARKETING, & SALES, INC. (361925498)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(64092-112)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(64092-112)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(64092-112)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(64092-112)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(64092-112)

Revised: 6/2023

GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.