XPECT PAIN AWAY EXTRA STRENGTH- acetaminophen aspirin caffeine tablet Cintas Corporation

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.

Xpect Pain Away Extra Strength

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: • a cold • toothache • headache • muscular aches • arthritis • 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 bahavior with nausea and vomiting occur, consult a doctor becuase 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: • shock • facial swelling • hives • 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

- 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
- are age 60 or older
- 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
- you have asthma
- 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

Ask a doctor or pharmacist before use if you are

- taking a precription 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
- 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
- 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 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 packet 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

Ouestions?

1-877-973-2811 Monday-Friday 8:00 AM-5:00 PM

Principal Display Panel - 42961-234-02

†Compare to the active ingredients of Excedrin®

EXTRA STRENGTH PAIN AWAY®

Active Ingredients:

Acetaminophen

Aspirin (NSAID)

Caffeine

Pain Reliever / Pain Reliever Aid

- Relief from headaches
- Contains caffeine

Xpect® First aid

WORKPLACE READY®

- Single Dose
- Tamper Evident

100 Tablets • 50 Packets (2 tablets per packet) per Box

†This product is not manufactured or distributed by GSK Consumer Healthcare SARL, owner of the registered trademark Excedrin \circledR .

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Principal Display Panel - 42961-234-03

†Compare to the active ingredients of Excedrin®

EXTRA STRENGTH PAIN AWAY®

Active Ingredients:

Acetaminophen

Aspirin (NSAID)

Caffeine

Pain Reliever / Pain Reliever Aid

- Relief from headaches
- Contains caffeine

Xpect® First aid

WORKPLACE READY®

- Single Dose
- Tamper Evident

250 Tablets • 125 Packets (2 tablets per packet) per Box

†This product is not manufactured or distributed by GSK Consumer Healthcare SARL,

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XPECT PAIN AWAY EXTRA STRENGTH

acetaminophen aspirin caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42961-234
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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 (UNII: 2S7830E561)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POVIDONE (UNII: FZ 989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	15mm	
Flavor		Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:42961-234- 02	50 in 1 BOX	07/26/2023		
1	NDC:42961-234- 01	2 in 1 PACKAGE; Type 0: Not a Combination Product			
2	NDC:42961-234- 03	125 in 1 BOX	07/26/2023		
2	NDC:42961-234- 01	2 in 1 PACKAGE; 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	07/26/2023	

Labeler - Cintas Corporation (056481716)

Establishment				
Name	Address	ID/FEI	Business Operations	
L.N.K. International Inc.		832867894	manufacture(42961-234)	

Revised: 7/2023 Cintas Corporation