HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)

Drug Facts

Active ingredients (in each geltab)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Pain reliever

Pain reliever aid

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - ∘ a cold
 - arthritis
 - muscular aches
 - toothache
 - 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: 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.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

hives

- facial swelling
- shock
- asthma (wheezing)

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 heartbeat.

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.

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 have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- you are taking a diuretic

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 doctor if

- an allergic reaction occurs. Seek medical help right away.
 - any new symptoms appear
- 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 loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- painful area is red or swollen

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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not use more than directed
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 geltabs every 6 hours; do not take more than 8 caplets in 24 hours
- children under 12 years: do not use unless directed by a doctor

Other information

store between 20º-25ºC (68º-77ºF)

Inactive ingredients

black printing ink,corn starch, D&C yellow #10 aluminum lake, edetate disodium, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, gelatin, glycerin, hydroxypropyl cellulose, hydroxypropyl cellulose-low substituted, hypromellose, iron oxide black, maltitol, povidone, purified water, stearic acid, talc, titanium dioxide

Questions or comments?

Call 1-888-309-9030

Principal Display Panel

Compare to the active ingredients of Excedrin® Extra Strength†

Extra Strength

Headache Relief

Acetaminophen/ Pain Reliever

Aspirin (NSAID)/ Pain Reliever

Caffeine/ Pain Reliever Aid

GELTABS

 \dagger This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Extra Strength.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

Package Label



HEADACHE RELIEF EXTRA STRENGTH

acetaminophen, aspirin, caffeine tablet

Product Information

	oduct Type		HUMAN OTC DRUG	Item Code (Source)		irce)	NDC:55910-686		
Ro	ute of Admir	ute of Administration ORAL							
٨٢	tive Ingred	lient/Active	Moiety						
			-			Bacic of St	trongth	Strongt	
					Basis of Str		-	250 mg	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36								250 mg	
ASPIRIN (UNII: R16C05Y76E) (ASPIRIN - UNII:R16C05Y76E) ASPIRIN CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) CAFFEIN						CAFFEINE		250 mg	
CA	FFEINE (ONII. 5	(C/		52)		CAFFEINE		05 mg	
Ina	active Ingr	edients							
		cultures	Ingredient Nan	ıe				Strength	
ST/	ARCH, CORN (U	JNII: 08232NY3S	-						
D&	C YELLOW NO	. 10 (UNII: 355V	V5USQ3G)						
		UM (UNII: 7FLD9							
		1 (UNII: H3R47K3							
FD	C RED NO. 4	0 (UNII: WZ B912	7XOA)						
GE	LATIN (UNII: 2G	86QN327L)							
GL	CERIN (UNII: P	DC6A3C0OX)							
HY	DROXYPROPYI	CELLULOSE,	UNSPECIFIED (UNII: 9XZ	8H6N6OH)					
HY	PROMELLOSES	6 (UNII: 3NXW29)	/3WO)						
FEF	RROSOFERRIC	OXIDE (UNII: XM	MOM87F357)						
МА	LTITOL (UNII: D	065DG142WK)							
PO	VIDONE (UNII:	FZ989GH94E)							
WATER (UNII: 059QF0KO0R)									
ST	EARIC ACID (UI	NII: 4ELV7Z65AP)						
ΤΑΙ	.C (UNII: 7SEV7	J4R1U)							
тіт		E (UNII: 15FIX9)	/2JP)						
HY	DROXYPROPYI	CELLULOSE, I	LOW SUBSTITUTED (UN	III: 2165RE0k	<14)				
		acteristics							
Color		-	(white) Score				no score		
Shape		CAPSUI				13mm			
Flavor				Imprint Code			Р		
Со	ntains								
Pa	ckaging								
#	ltem Code	Pa	ackage Description			eting Start Date		eting End Date	
	NDC:55910- 586-20	1 in 1 BOX			03/31/20	19			
		20 in 1 BOTTLE	, PLASTIC; Type 0: Not a						
1		Combination Pr	roduct						

Marketing Information									
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date						
OTC Monograph Drug	M013	03/31/2019							

Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)

Revised: 3/2024

Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)