# HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet Safeway, Inc.

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#### **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 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 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.
- you experience any of the following signs of stomach bleeding
  - o 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
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts more than 3 days
- any 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 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 geltabs in 24 hours
- children under 12 years: do not use unless directed by a doctor

#### Other information

• store between 20°-25°C (68°-77°F)

#### **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 1-877-753-3935 Monday-Friday 9AM-5PM EST

#### **Principal Display Panel**

COMPARE TO Excedrin® Extra Strength active ingredients†
Extra Strength

Headache Relief

ACETAMINOPHEN 250 mg

ASPIRIN (NSAID) 250 mg

CAFFEINE 65 mg

Pain Reliever/Pain Reliever Aid

**GELTABS** 

†This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, 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
BETTER LIVING BRANDS LLC
P.O. BOX 99
PLEASANTON, CA 94566-0009

Package Label green

LLC, distributor of Excedrin® Extra Strength. GlaxoSmithKline Consumer Healthcare Holdings (US) \*This product is not manufactured or distributed by

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

WARNINGS AND PRODUCT INFORMATION KEEP OUTER CARTON FOR COMPLETE







Scan here for more information



# are. Strength

COMPARE TO xcedrin Extra

NDC 21130-586-20

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These could be signs of a serious condition. asts for more than 3 days any new symptoms occur worse or lasts for more than 10 days 
fever gets worse or

hearing occurs painful area is red or swollen

pain gets

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get

child or complications during delivery

Extra Strength

leadac

(in each geltab) Active ingredients

'nonsteroidal anti-inflammatory drug

■ toothache
■ premenstrual and menstrual cramps ■ headache ■ a cold ■ arthritis ■ muscular aches

because these symptoms could be an early sign of Reye's behavior with nausea and vomiting occur, consult a doctor use this product. When using this product, if changes in syndrome, a rare but serious illness. ecovering from chicken pox or flu-like symptoms should not Reye's syndrome: Children and teenagers who have or are

■ 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 ■ hives ■ facial swelling ■ shock ■ asthma (wheezing) seek medical help right away. Allergy alert: Aspirin may cause a severe allergic reaction, which may include: ■ blisters ■ rash. If a skin reaction occurs, stop use and Allergy alert: Acetaminophen may cause severe skin NSAID, which may cause severe stomach bleeding. The Severe liver damage may occur if you take: **Liver warning:** This product contains acetaminophen. eactions. Symptoms may include: skin reddening omach bleeding warning: This product contains an

> taking a prescription drug for diabetes, gout, or arthritis Ask a doctor or pharmacist before use if you are

Inactive ingredients black printing ink, corn starch, D&C yellow #10 aluminum lake, edetate disodium, FD&C blue

glycerin, hydroxypropyl cellulose, hydroxypropyl cellulose-low substituted, hypromellose, iron oxide black, maltitol, povidone

aluminum lake, FD&C red #40 aluminum lake, gelatin,

purified water, stearic acid, talc, titanium dioxide

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

20 GELTABS

Actual Size

chance is higher if you:

■ are age 60 or older

PLEASANTON, CA 94566-0009

1-888-723-3929

RD 24030

10823

Lot No.:

PLD-8514C

FC008572 Exp. Date:

P.O. BOX 99

100% GUARANTEED

OUR PROMISE

DISTRIBUTED BY BETTER LIVING BRANDS LLC

uestions or comments?

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Pain Reliever/Pain Reliever Aid

CAFFEINE 65 mg

ASPIRIN (NSAID) 250 mg ACETAMINOPHEN 250 mg

Other information

a full glass of water with each dose adults and children 12

UITECTIONS ■ do not use more than directed

■ drink

Relief

notice any signs or symptoms

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use unless directed by a doctor

**Drug Facts** 

Purposes

Caffeine 65 mg. pirin 250 mg (NSAID) Pain reliever aid Pain relieve

USES temporarily relieves minor aches and pains due to

cause nervousness, irritability, sleeplessness, and, while taking this product because too much caffeine may use of caffeine-containing medications, toods, or beverages contains about as much caffeine as a cup of coffee. Limit the

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

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

Stop use and ask a doctor if an allergic reaction occurs that does not get better ringing in the ears or loss of ■ vomit

Drug Facts (continued)

have had stomach ulcers or bleeding problems Caffeine warning: The recommended dose of this product more or for a longer time than directed drugs containing prescription or nonprescription NSAIDs blood thinning (anticoagulant) or steroid drug ■ take other alcoholic drinks every day while using this product [aspirin, ibuprofen, naproxen, or others] 

have 3 or more ■ take a ■ take

occasionally, rapid heartbeat

following signs of stomach bleeding ■ feel faint ■ w blood ■ have bloody or black stools ■ have stomach Seek medical help right away. 

you experience any of the serious condition taking any other drug or are under a doctor's care for any

SIGNATURE CARE Extra Strength Headache Relief

Package label

LLC, distributor of Excedrin® Extra Strength. GlaxoSmithKline Consumer Healthcare Holdings (US) This product is not manufactured or distributed by IPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.





Scan here for more information

# Extra Strength

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NDC 21130-586-20

Strength COMPARE TO

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JIFECTIONS and not use more than directed

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Pain Reliever/Pain Reliever Aid

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Headac

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Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

20 GELTABS

Actual Size

DISTRIBUTED BY BETTER LIVING BRANDS LLC P.O. BOX 99

100% GUARANTEED OUR PROMISE

PLEASANTON, CA 94566-0009 1-888-723-3929

RD 24030

10828

Lot No.: PLD-8514C

Exp. Date: FC008573 estions or comments?

purified water, stearic acid, talc, titanium dioxide

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(in each geltab) Active ingredients 50 mg (NSAID Purposes 4 6 1

nonsteroidal anti-inflammatory

Pain reliever aid

 premenstrual and menstrual cramps muscular aches

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Drug Facts (continued

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take other ■ take a

SIGNATURE CARE Extra Strength Headache Relief

#### HEADACHE RELIEF EXTRA STRENGTH

acetaminophen, aspirin, caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-586
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
MALTITOL (UNII: D65DG142WK)	
WATER (UNII: 059QF0KO0R)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	

Product Characteristics			
Color	white (green/white)	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	Р
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:21130- 586-20	1 in 1 CARTON	04/18/2022	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	

Category	Citation	Date	Date
OTC Monograph Drug	M013	04/18/2022	

### Labeler - Safeway, Inc. (009137209)

Revised: 2/2024 Safeway, Inc.