

TENSION HEADACHE ASPIRIN FREE- acetaminophen, caffeine tablet, film coated
CVS Pharmacy

CVS 44-428

Active ingredients (in each caplet)

Acetaminophen 500 mg
(formulated with 65 mg caffeine)

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches

Warnings

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

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

- blisters
- rash
- skin reddening

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

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

- 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 are allergic to acetaminophen

Ask a doctor before use if you have

liver disease.

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- new symptoms occur
- painful area is red or swollen
- 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.

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**
- adults and children 12 years and over: take 2 caplets every 6 hours. Do not take more than 6 caplets 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)
- use by expiration date on package

Inactive ingredients

corn starch, crospovidone, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

**♥CVS
Health™**

Compare to the active ingredients
in Excedrin® Tension Headache*

Coated Caplets

**Aspirin Free
Tension Headache**

**ACETAMINOPHEN
& CAFFEINE
Pain reliever**

100 CAPLETS

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 S.A.,
owner of the registered trademark Excedrin® Tension Headache.

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One CVS Drive, Woonsocket, RI 02895

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1-800-SHOP CVS V-11112

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Compare to the active ingredients in Excedrin® Tension Headache*

Coated Caplets

Aspirin Free

Tension Headache

ACETAMINOPHEN & CAFFEINE

Pain reliever

100 CAPLETS



Actual Size



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

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg. Pain reliever (formulated with 65 mg caffeine)

Uses

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 - headache
 - muscular aches

Warnings

- 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

No Print / No Varnish Area Lot # and Exp. Info

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1-800-SHOP CVS V-11112

#693411



50844

REV119A42812

FPO 80%

UPC# 050428385449

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PEEL HERE FOR MORE DRUG FACTS

Drug Facts (continued)

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

- hives
- rash
- skin reddening

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

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

- 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 are allergic to acetaminophen

Ask a doctor before use if you have liver disease.

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

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STOP PEELING

Drug Facts (continued)

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Questions or comments?

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CVS 44-428

TENSION HEADACHE ASPIRIN FREE

acetaminophen, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-824
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPROVIDONE (UNII: 2S7830E561)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	44;428
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-824-21	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/17/2007	
2	NDC:59779-824-06	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/17/2007	
3	NDC:59779-824-08	1 in 1 CARTON	01/17/2007	12/01/2024
3		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:59779-824-12	1 in 1 CARTON	01/17/2007	02/11/2018
4		100 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	01/17/2007	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(59779-824)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(59779-824)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(59779-824)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(59779-824)

Revised: 7/2023

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