

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

CVS Pharmacy

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.

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

- pain gets worse or lasts for more than 10 days
- new symptoms occur
- 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.

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 use 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 aluminium 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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1-800-SHOP CVS V-11112



Compare to the active ingredients
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Coated Caplets

Aspirin Free

Tension Headache

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Drug Facts

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(formulated with 65 mg caffeine)

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

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hours
■ with other drugs containing acetaminophen
■ 3 or more alcoholic drinks every day while using
this product

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

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PEEL HERE FOR MORE DRUG FACTS



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Drug Facts (continued)

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STOP PEELING

Drug Facts (continued)

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Inactive ingredients

corn starch,
croscopolone, 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?

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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	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)					
TALC (UNII: 7SEV7J4R1U)					
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)					
STARCH, CORN (UNII: O8232NY3SJ)					
STEARIC ACID (UNII: 4ELV7Z65AP)					
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)					
CROSPOVIDONE (UNII: 2S7830E561)					
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)					
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)					
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:59779-824-12	1 in 1 CARTON	01/17/2007	02/11/2018	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:59779-824-08	1 in 1 CARTON	01/17/2007		
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
3	NDC:59779-824-06	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/17/2007		
4	NDC:59779-824-21	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/17/2007		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	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: 3/2020

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