

PAIN RELIEF PM- acetaminophen, aspirin, diphenhydramine citrate tablet, film coated
CVS Pharmacy

CVS 44-674

Active ingredients (in each caplet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Diphenhydramine citrate 38 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Pain reliever

Nighttime sleep-aid

Uses

for the temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

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

- hives
- facial swelling
- shock
- asthma (wheezing)

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.

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
- take more or for a longer time than directed
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- have 3 or more alcoholic drinks every day while using this product

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.
- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have difficulty in urination due to enlargement of the prostate gland
- you have liver disease
- you have a breathing problem such as emphysema or chronic bronchitis
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have glaucoma
- you have asthma

Ask a doctor or pharmacist before use if you are taking

- a prescription drug for:
 - diabetes
 - gout
 - arthritis
- any other drug, or are under a doctor's care for any serious condition
- sedatives or tranquilizers
- any product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

When using this product

- avoid alcoholic beverages
- drowsiness may occur
- do not drive a motor vehicle or operate machinery

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
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- pain gets worse or lasts for more than 10 days
- redness or swelling is present
- 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**
- adults and children 12 years and over: take 2 caplets at bedtime, with a full glass of water
- do not take more than 2 caplets in 24 hours, unless directed by a doctor
- children under 12 years: do not use

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, crospovidone, FD&C blue #1 aluminum lake, hypromellose, maltodextrin, medium chain triglycerides, microcrystalline cellulose, polydextrose, povidone, sodium lauryl sulfate, sodium starch glycolate, sodium sulfate, stearic acid, talc, titanium dioxide, yellow iron oxide, zinc stearate

Questions or comments?

1-800-426-9391

Principal Display Panel

♥CVSHealth®

Compare to the active ingredients
in Excedrin® PM Headache†

Caplets

Pain Relief PM

ACETAMINOPHEN, 250 mg

ASPIRIN (NSAID), 250 mg

DIPHENHYDRAMINE CITRATE, 38 mg

Pain reliever, Nighttime sleep-aid

- Non-habit forming
- For pain with sleeplessness

100 CAPLETS

Actual Size

Package Contains One Bottle

**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 SARL, owner of the registered
trademark Excedrin® PM Headache.

50844 REV1121A67412

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Nighttime Headache Relief

CVS Health.

Compare to the active ingredients in Excedrin® PM Headache†

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Pain Relief PM

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Pain Relief PM

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Pain reliever, Nighttime sleep-aid

- Non-habit forming
- For pain with sleeplessness



Actual Size

Package Contains One Bottle

100 CAPLETS

BG879L3
Z FOLD

B-0231-674-12-HR
REV1121A67412

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking:
 ■ prescription drug for ■ gout ■ asthma
 ■ other drug, or are under a doctor's care for any serious
 condition ■ sedatives or tranquilizers
 ■ any product that contains aspirin, acetaminophen, or any other
 pain reliever/fever reducer
When using this product
 ■ avoid alcoholic beverages ■ drowsiness may occur
 ■ do not drive a motor vehicle or operate machinery
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 ■ vomit blood
 ■ have bloody or black stools
 ■ have stomach pain that does not get better
 ■ ringing in the ears or a loss of hearing occurs
 ■ sleepiness persists continuously for more than 2 weeks.
 ■ insomnia may be a symptom of a serious underlying medical
 illness.

Drug Facts (continued)

■ gain gets worse or lasts for more than 10 days
 ■ redness or swelling is present ■ 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
 ■ adults and children 12 years and over: take 2 caplets at bedtime.
 ■ with a full glass of water
 ■ do not take more than 2 caplets in 24 hours, unless directed by a
 doctor
 ■ children under 12 years: do not use

Drug Facts (continued)

Warnings
 ■ eye's symptoms: Children and teenagers who have or are
 recovering from chicken pox or flu-like symptoms should not
 use this product. When using this product, it 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.
 Allergic alert: Aspirin may cause a severe allergic reaction,
 which may include: ■ hives ■ facial swelling ■ shock
 ■ asthma (wheezing)
 ■ other allergic reactions
 Symptoms may include:
 ■ dizziness ■ rash ■ skin reddening
 ■ a skin reaction occurs, stop use and seek medical help right
 away.

Uses
 ■ for the temporary relief of occasional headaches and
 minor aches and pains with accompanying sleeplessness
 ■ as a temporary anti-inflammatory drug

Other Information
 ■ contains 100 caplets
 ■ contains 250 mg (NSAID)
 ■ pain reliever
 ■ nighttime sleep-aid

Drug Facts (continued)

Active Ingredients (in each caplet) Purpose
 Acetaminophen 250 mg
 Aspirin 250 mg (NSAID)
 Diphenhydramine citrate 38 mg
 Pain reliever
 Nighttime sleep-aid

Drug Facts (continued)

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
 ■ with other drugs containing acetaminophen
 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
 ■ take more or for a longer time than directed
 ■ take other drugs containing aspirin, or NSAIDs (aspirin, ibuprofen, naproxen, or others)
 ■ have 3 or more alcoholic drinks every day while using this product
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
 over-the-counter), if you are not sure whether a drug contains
 acetaminophen, aspirin, or a doctor or pharmacist.
Ask a doctor before use if
 ■ you have a history of stomach problems, such as heartburn
 ■ stomach bleeding warning applies to you
 ■ you have difficulty in urination due to enlargement of the prostate
 gland
 ■ you have a breathing problem such as emphysema or chronic
 bronchitis
 ■ you are taking a diuretic
 ■ you have high blood pressure, heart disease, liver cirrhosis, or
 kidney disease
 ■ you have glaucoma
 ■ you have asthma

Other Information
 ■ see end flap for expiration date and lot number
 ■ store at 25°C (77°F); excursions permitted between 15°-30°C
 (59°-86°F)
 ■ FDIC blue #1 aluminum lake, hypromellose, maltodextrin,
 medium chain triglycerides, microcrystalline cellulose,
 polydextrose, povidone, sodium lauryl sulfate, sodium starch
 glycolate, sodium sulfate, stearic acid, talc, titanium dioxide,
 yellow iron oxide, zinc stearate
Questions or comments? 1-800-426-9391
 This product is not manufactured or distributed by
 GSK Consumer Healthcare S-APL, owner of the registered
 trademark Excedrin® PM Headache.
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**TAMPER EVIDENT: DO NOT USE IF IMPRINTED
 SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

#6933997



LOT/EXP "NO PRINT"

CVS 44-674

KEEP OUTER PACKAGE
 FOR COMPLET
 PRODUCT INFORMATION

PAIN RELIEF PM

acetaminophen, aspirin, diphenhydramine citrate tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-894
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ZINC STEARATE (UNII: H92E6QA4FV)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	674
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 59779-894			

1	NDC:59779-894-12	1 in 1 CARTON	08/31/2016	
1		100 in 1 BOTTLE; 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		08/31/2016	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(59779-894)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(59779-894)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(59779-894)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(59779-894)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(59779-894)

Revised: 7/2023

CVS Pharmacy