

PAIN RELIEF EXTRA STRENGTH- acetaminophen 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.

Pain Reliever

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - headache
 - backache
 - the common cold
 - toothache
 - minor pain of arthritis
 - premenstrual and menstrual cramps
- temporarily reduces fever

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:

- rash
- skin reddening
- blisters

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

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 or any of the inactive ingredients in this product.

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

- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur

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 (1-800-222-1222) 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 while symptoms last
 - do not take more than 6 caplets in 24 hours, unless directed by a doctor
 - do not take for more than 10 days unless directed by a doctor
- 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

castor oil, hypromellose, povidone, sodium starch glycolate, starch, stearic acid

Questions or comments?

1-800-426-9391

Principal Display Panel

♥ CVS
Health™

Compare to the active ingredient in Extra Strength Tylenol®*

Caplets

TAMPER EVIDENT: Use Only if This Blister is Intact

NDC 59779-751-03

EXTRA STRENGTH

Pain Relief

ACETAMINOPHEN, 500 mg

Pain reliever / Fever reducer

Aspirin free

10 **CAPLETS** Actual Size

Travel Pack

†This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol®.

50844 REV0617A17503

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Compare to the active ingredient in Extra Strength Tylenol®*

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Pain reliever, Fever reducer

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10 CAPLETS Actual Size

Travel Pack

No Varnish / Copy Free Area

No Print / No Varnish Area

Lot & Exp. Area

Drug Facts RETAIN VIAL CARD FOR COMPLETE PRODUCT INFORMATION

Active ingredient (in each caplet) Purpose
Acetaminophen 500 mg Pain reliever/fever reducer

Uses ■ temporarily relieves minor aches and pains due to: ■ muscular aches ■ headache
■ backache ■ the common cold
■ toothache ■ minor pain of arthritis
■ premenstrual and menstrual cramps
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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:
■ rash ■ skin reddening ■ blisters
If a skin reaction occurs, stop use and seek medical help right away.
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 or any of the inactive ingredients in this product

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
■ redness or swelling is present
■ pain gets worse or lasts more than 10 days
■ fever gets worse or lasts more than 3 days
■ new symptoms occur
These could be signs of a serious condition.

Drug Facts (continued)

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 (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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■ use by expiration date on package

Inactive ingredients castor oil, hypromellose, povidone, sodium starch glycolate, starch, stearic acid

Questions or comments?
1-800-426-9391

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CVS Health 44-175

PAIN RELIEF EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-751
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CASTOR OIL (UNII: D5340Y2I9G)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	44;175
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-751-03	1 in 1 PACKAGE	04/02/1993	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59779-751-96	2 in 1 PACKAGE	04/02/1993	
2		10 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59779-751-29	1 in 1 CARTON	04/02/1993	10/20/2015
3		150 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 NOT FINAL	part343	04/02/1993	

Labeler - CVS Pharmacy (062312574)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(59779-751)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(59779-751) , PACK(59779-751)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(59779-751)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(59779-751)

Revised: 8/2019

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