

PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet

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 44-519

Active ingredient (in each gelcap)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 gelcaps (3,000 mg) in 24 hours. 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:

- skin reddening
- blisters
- rash

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

Do not use

- if you are allergic to acetaminophen or any of the inactive ingredients in this product
- 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.

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

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 of symptoms.

Directions

- **do not take more than directed**
- adults and children 12 years and over
 - take 2 gelcaps every 6 hours while symptoms last
 - do not take more than 6 gelcaps 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)
- avoid high humidity
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, D&C red #33, FD&C blue #1, FD&C red #40, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

CVS Health™

Compare to the active ingredient in Extra Strength Tylenol® Rapid Release Gels*

Rapid Release Gelcaps

NDC 59779-519-20

EXTRA STRENGTH

Pain Relief

ACETAMINOPHEN, 500 mg

Pain reliever / Fever reducer

Aspirin free

225 GELCAPS

RAPID

RELEASE

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 McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels. 50844 ORG061551920

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1-800-SHOP CVS V-11112

✓ **CVS Quality**

Money Back Guarantee

No Print/No Varnish
Lot & Expiry Area

320324

FPD 100%

UPC# 050428382295

X XXXXXX XXXXXX X

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

225 GELCAPS

Aspirin free

Pain reliever, Fever reducer

Pain Relief

EXTRA STRENGTH

ACETAMINOPHEN, 500 mg

CVS Health

Rapid Release Gels

B-0231-519-20-H

ORG061551920

Package Contains One Bottle

Actual Size

No Print
Glue Area

No Print
Glue Area

CVS Health.

Compare to the active ingredient in Extra Strength Tylenol® Rapid Release Gels*

Rapid Release Gels

NDC 59779-519-20

EXTRA STRENGTH

Pain Relief

ACETAMINOPHEN, 500 mg

Pain reliever, Fever reducer

Aspirin free

225 GELCAPS

Actual Size

RAPID RELEASE

No Print
Glue Area

No Print/No Varnish
Lot & Expiry Area

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient (in each gelcap)
Acetaminophen 500 mg, ... Pain reliever/fever reducer

Purpose

Uses

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

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- 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:

- skin redness
- hives
- itching
- swelling of the face, lips, tongue, or throat
- difficulty breathing
- skin rash

Do not use

- if you are allergic to acetaminophen or any of the inactive ingredients in this product
- 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.

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

Stop use and ask a doctor if

- your pain gets worse or lasts more than 10 days

No Print/No Varnish
Lot & Expiry Area

No Print/No Varnish
Lot & Expiry Area

Drug Facts (continued)

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

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Questions or comments? 1-800-426-9391

This product is not manufactured or distributed by Medical Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels.

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1-800-SAVE-CVS 1-112

CVS Quality
Doing More. Smarter.

FLUZE REUSE

No Print/No Varnish
Lot & Expiry Area

CVS Health 44-519

PAIN RELIEF EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-519
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SHELLAC (UNII: 46N107B71O)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	RED, BLUE	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-519-08	1 in 1 CARTON	05/10/2004	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59779-519-12	1 in 1 CARTON	05/10/2004	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:59779-519-15	1 in 1 CARTON	05/10/2004	
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:59779-519-20	1 in 1 CARTON	05/10/2004	
4		225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

5	NDC:59779-519-29	1 in 1 CARTON	05/10/2004	
5		150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:59779-519-05	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2004	
7	NDC:59779-519-89	225 in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/10/2004	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(59779-519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(59779-519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(59779-519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(59779-519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(59779-519)

Revised: 12/2018

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