ACETAMINOPHEN EXTRA STRENGTH- acetaminophen capsule
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 Acetaminophen

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. 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 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 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- 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

EXTRA STRENGTH
ACETAMINOPHEN, Gelcaps, 500 mg

Pain reliever, Fever reducer
Aspirin free

225 GELCAPS

RAPID
RELEASE

Actual Size

Actual Bottle Size on Top Panel

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

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels.
50844 ORG041751920

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895

1-800-SHOP CVS V-11112

√ **CVS® Quality**
Money Back Guarantee

CVS 44-519

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-915
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:69842-915-20	1 in 1 CARTON	02/20/2020	
1		225 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-915-15	1 in 1 CARTON	02/20/2020	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69842-915-08	1 in 1 CARTON	02/20/2020	
3		24 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69842-915-12	1 in 1 CARTON	02/20/2020	
4		100 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69842-915-05	400 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	
6	NDC:69842-915-29	150 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	
7	NDC:69842-915-78	600 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC MONOGRAPH NOT FINAL	part343	02/20/2020	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(69842-915) , PACK(69842-915)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(69842-915)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(69842-915)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(69842-915)

Revised: 2/2020 CVS Pharmacy