ACETAMINOPHEN 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.

CVS 44-531C

Active ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - toothache
  - muscular aches
  - backache
  - the common cold
  - 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:

- blisters
- rash
- skin reddening

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

- 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 or symptoms.

Directions

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

Inactive ingredients

corn starch, D&C red #27 aluminum lake, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, polyethylene glycol, polyvinyl alcohol, povidone, sodium starch glycolate*, stearic acid, sucralose, talc, titanium dioxide

*may contain this ingredient

Questions or comments?

1-800-426-9391

Principal display panel

CVSHealth™

Compare to the active ingredient
in Extra Strength Tylenol®*

Easy to Swallow Tablets

EXTRA STRENGTH

Acetaminophen

Tablets, 500 mg

Pain reliever, Fever reducer

Aspirin free, Sweet coating

24 FILM COATED TABLETS

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 Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol®. 50844 REV1018A53108

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

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V-11112

CVS®Quality
Money Back Guarantee

CVS Health 44-531C

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-931
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
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	44;531
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-931-08	1 in 1 CARTON	12/11/2005	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:69842-931-17	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2005	
3	NDC:69842-931-29	150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	12/11/2005	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations

LNK International, Inc.		832867837	MANUFACTURE(69842-931)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(69842-931)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(69842-931)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(69842-931)

Revised: 2/2020 CVS Pharmacy