PAIN RELIEF EXTRA STRENGTH- acetaminophen capsule, liquid filled
CVS PHARMACY, INC.

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 Relief Extra Strength

Drug Facts

Active ingredient (in each softgel)

Acetaminophen 500 mg

Purpose

Pain reliever/ fever reducer

Uses

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

- 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.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick 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** (see **Overdose warning**)

Adults and children 12 years and over	• take 2 softgels every 6 hours while symptoms last • do not take more than 6 softgels in 24 hours unless directed by a doctor • do not use for more than 10 days unless directed by a doctor
Children 12 years	ask a doctor

Other information

- store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special and white edible ink

Questions or Comments?

Call toll free **1-855-215-8180**

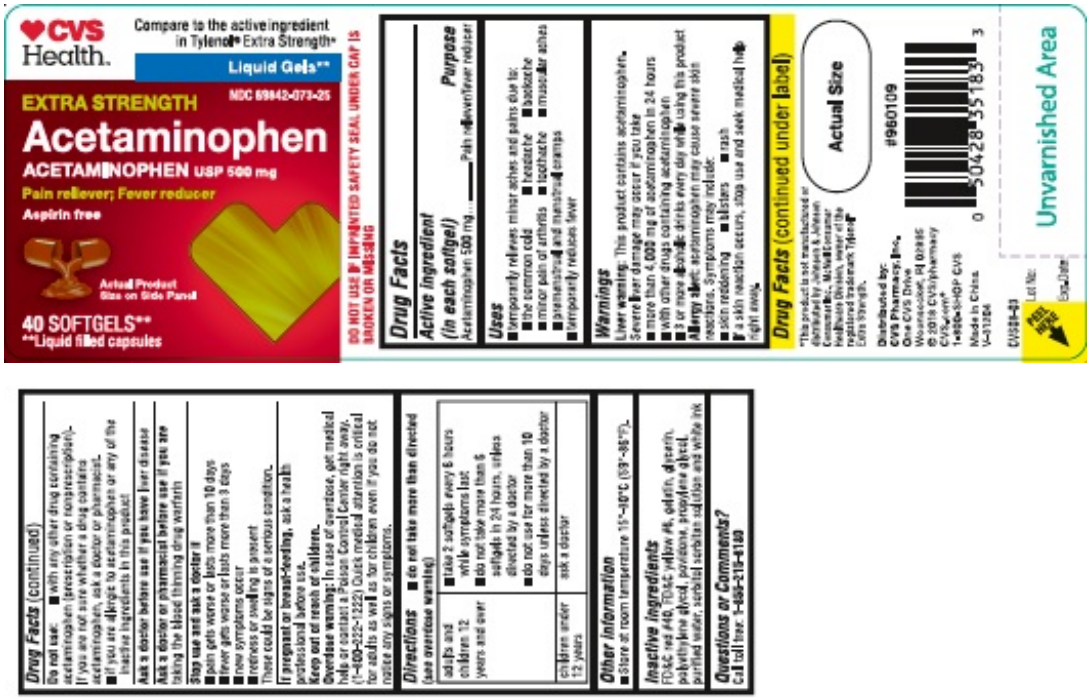
PRINCIPAL DISPLAY PANEL - 40ct Bottle Label

EXTRA STRENGTH PAIN RELIEF

ACETAMINOPHEN 500 mg 40 Liquid Gels

NDC 69842-073-25

Compare to the active ingredient in TYLENOL® Extra Strength



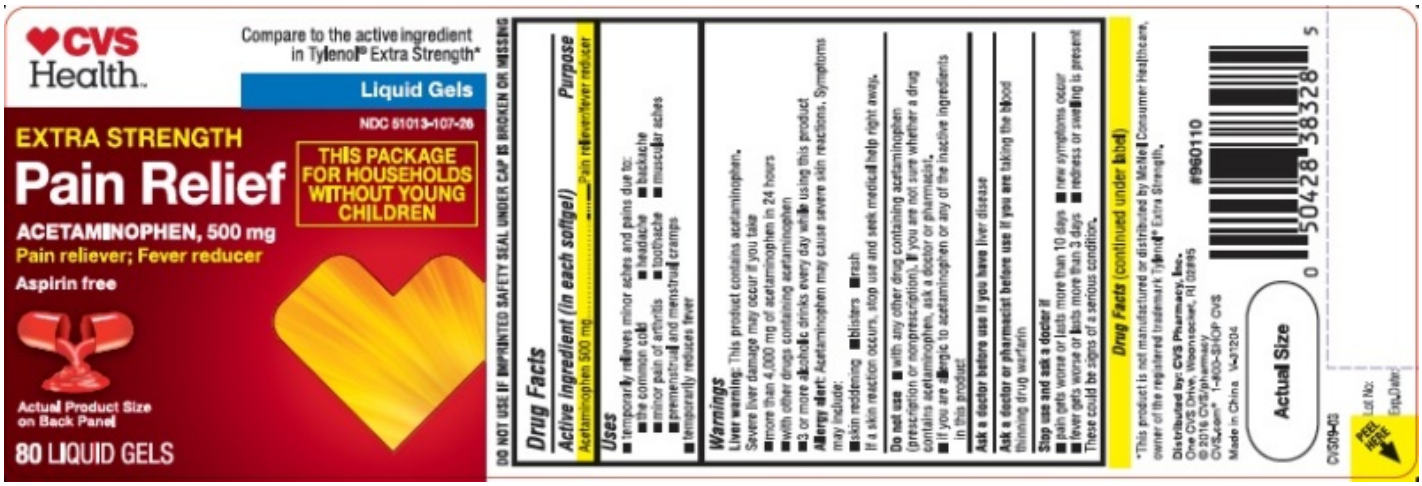
PRINCIPAL DISPLAY PANEL - 80ct Bottle Label

EXTRA STRENGTH PAIN RELIEF

ACETAMINOPHEN 500 mg 80 Liquid Gels

NDC 69842-073-26

Compare to the active ingredient in TYLENOL® Extra Strength



Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children.
Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick 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** (see **Overdose warning**)

adults and children 12 years and over	■ take 2 softgels every 6 hours while symptoms last ■ do not take more than 6 softgels in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

Other information
- store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special and white edible ink

Questions or comments? Call toll free 1-855-215-8180

PAIN RELIEF EXTRA STRENGTH

acetaminophen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-073
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**
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	red (Clear Red)	**Score**	no score
Shape	CAPSULE (oblong)	**Size**	24mm
Flavor		**Imprint Code**	PC24
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-073-25	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/14/2016	
2	NDC:69842-073-26	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/14/2016	

Labeler - CVS PHARMACY, INC. (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	MANUFACTURE(69842-073) , ANALYSIS(69842-073)

Revised: 11/2019 CVS PHARMACY, INC.