

CVS HEALTH EXTRA STRENGTH ACETAMINOPHEN SOFTGELS-

acetaminophen capsule, liquid filled

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 Health Extra Strength Acetaminophen Softgels

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.

- 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 under 12 years	ask a doctor

Other information

- **each softgel contains:** sodium 7 mg
- store between 15°-30°C (59°-86°F)

Inactive ingredients

FD&C Red #40, gelatin, glycerin, polyethylene glycol 400, potassium hydroxide, povidone, propylene glycol, purified water, sodium hydroxide, sorbitol, sorbitol sorbitan solution titanium dioxide

Questions or Comments? 1-888-333-9792

PRINCIPAL DISPLAY PANEL

CVS Health

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

EXTRA STRENGTH

Acetaminophen USP 500mg

Pain Reliever; Fever reducer

Aspirin free

40 SOFTGELS**

**Liquid filled capsules

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 Tylenol® Extra Strength.

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Drug Facts (continued)

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
- nausea 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
 - 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

- each softgel contains: sodium 7 mg
- store between 15°-30°C (59°-86°F)

Inactive ingredients
 FD&C Red #40, gelatin, glycerin, polyethylene glycol 400, potassium hydroxide, povidone, propylene glycol, purified water, sodium hydroxide, sorbitol, sorbitol sorbitan solution, titanium dioxide

Questions or comments? 1-888-333-9792

CVS HEALTH EXTRA STRENGTH ACETAMINOPHEN SOFTGELS

acetaminophen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-636
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)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POTASSIUM HYDRO XIDE (UNII: WZH3C48M4T)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIO XIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red (transparent)	Score	no score
Shape	OVAL	Size	23mm
Flavor	GRAPE	Imprint Code	710
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-636-40	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/05/2019	

Labeler - CVS Pharmacy (062312574)**Registrant** - Spirit Pharmaceuticals LLC (179621011)**Establishment**

Name	Address	ID/FEI	Business Operations
MEDGEL PRIVATE LTD		677385498	manufacture(69842-636)

Revised: 6/2019

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