

REGULAR STRENGTH PAIN RELIEF- 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.

Regular Strength Pain Relief

Drug Facts

Active ingredient (in each softgel)

Acetaminophen 325 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 softgels (3,250 mg) in 24 hours for adults or 5 softgels (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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	<ul style="list-style-type: none"> • take 2 softgels every 4 to 6 hours while symptoms last • do not take more than 10 softgels in 24 hours • do not use for more than 10 days unless directed by a doctor
children 6-11 years	<ul style="list-style-type: none"> • take 1 softgel every 4 to 6 hours while symptoms last • do not take more than 5 softgels in 24 hours • do not use for more than 5 days unless directed by a doctor
children under 6 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 - 20ct Carton and Bottle Label

CVS Regular Strength Pain Relief
 ACETAMINOPHEN 325 mg 20 LIQUID GELS
 NDC 69842-075-15

*Compare to the active ingredient in **TYLENOL®** Regular Strength

Drug Facts (continued)

In some cases, acetaminophen may cause liver damage, especially if you take too much. If you take more than the recommended dose, you may experience symptoms such as nausea, vomiting, loss of appetite, stomach pain, loss of weight, and yellowing of the skin or eyes. If you experience any of these symptoms, stop taking this product and call your healthcare provider.

Do not take more than 4,000 mg of acetaminophen in 24 hours. Do not take more than 6,000 mg of acetaminophen in 24 hours if you are taking this product in combination with other acetaminophen-containing products.

Some people may be more sensitive to acetaminophen than others. Do not take more than the recommended dose.

Do not take more than 2 doses in 24 hours. Do not take more than 4,000 mg of acetaminophen in 24 hours.

Do not take more than 6,000 mg of acetaminophen in 24 hours if you are taking this product in combination with other acetaminophen-containing products.

Do not take more than 2 doses in 24 hours. Do not take more than 4,000 mg of acetaminophen in 24 hours.

Do not take more than 6,000 mg of acetaminophen in 24 hours if you are taking this product in combination with other acetaminophen-containing products.

CVS Health

Regular Strength Pain Relief

ACETAMINOPHEN 325 mg
 Pain reliever; Fever reducer
 Contains no aspirin

20 LIQUID GELS

Actual Product Size
 See Side Panel

Drug Facts

Active ingredient (for each softgel):
 Acetaminophen 325 mg

Other ingredients:
 Hydroxypropyl methylcellulose, croscarmellose sodium, polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 800, polyethylene glycol 1000, polyethylene glycol 1500, polyethylene glycol 2000, polyethylene glycol 3000, polyethylene glycol 4000, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000, polyethylene glycol 15000, polyethylene glycol 20000, polyethylene glycol 30000, polyethylene glycol 40000, polyethylene glycol 60000, polyethylene glycol 80000, polyethylene glycol 100000.

Warnings:
 Do not take more than 4,000 mg of acetaminophen in 24 hours. Do not take more than 6,000 mg of acetaminophen in 24 hours if you are taking this product in combination with other acetaminophen-containing products.

Directions:
 Adults and children 12 years and over: Take 1 softgel every 4 to 6 hours while symptoms last. Do not take more than 10 softgels in 24 hours. Do not use for more than 10 days unless directed by a doctor.

Other information:
 This product is not manufactured or distributed by the WellCo Consumer Healthcare, a division of Pharmacia Corporation, Kalamazoo, MI 49001. © 2014 CVS Health. All rights reserved. Made in China.

CVS Health

Regular Strength Pain Relief

ACETAMINOPHEN 325 mg
 Pain reliever; Fever reducer
 Contains no aspirin

20 LIQUID GELS

Warnings:
 Do not take more than 4,000 mg of acetaminophen in 24 hours. Do not take more than 6,000 mg of acetaminophen in 24 hours if you are taking this product in combination with other acetaminophen-containing products.

Directions:
 Adults and children 12 years and over: Take 1 softgel every 4 to 6 hours while symptoms last. Do not take more than 10 softgels in 24 hours. Do not use for more than 10 days unless directed by a doctor.

Other information:
 This product is not manufactured or distributed by the WellCo Consumer Healthcare, a division of Pharmacia Corporation, Kalamazoo, MI 49001. © 2014 CVS Health. All rights reserved. Made in China.

Actual Size

CVS Health

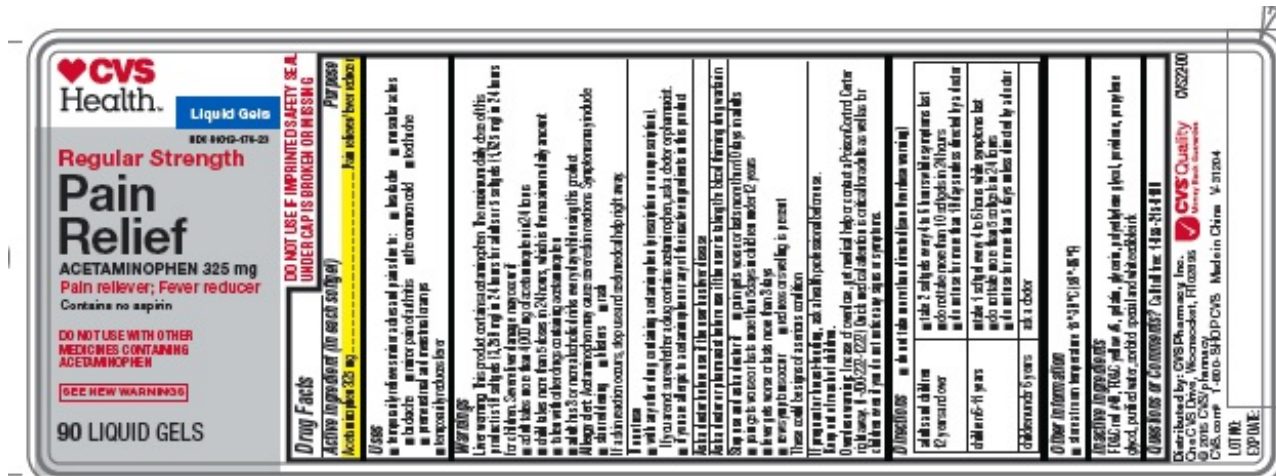
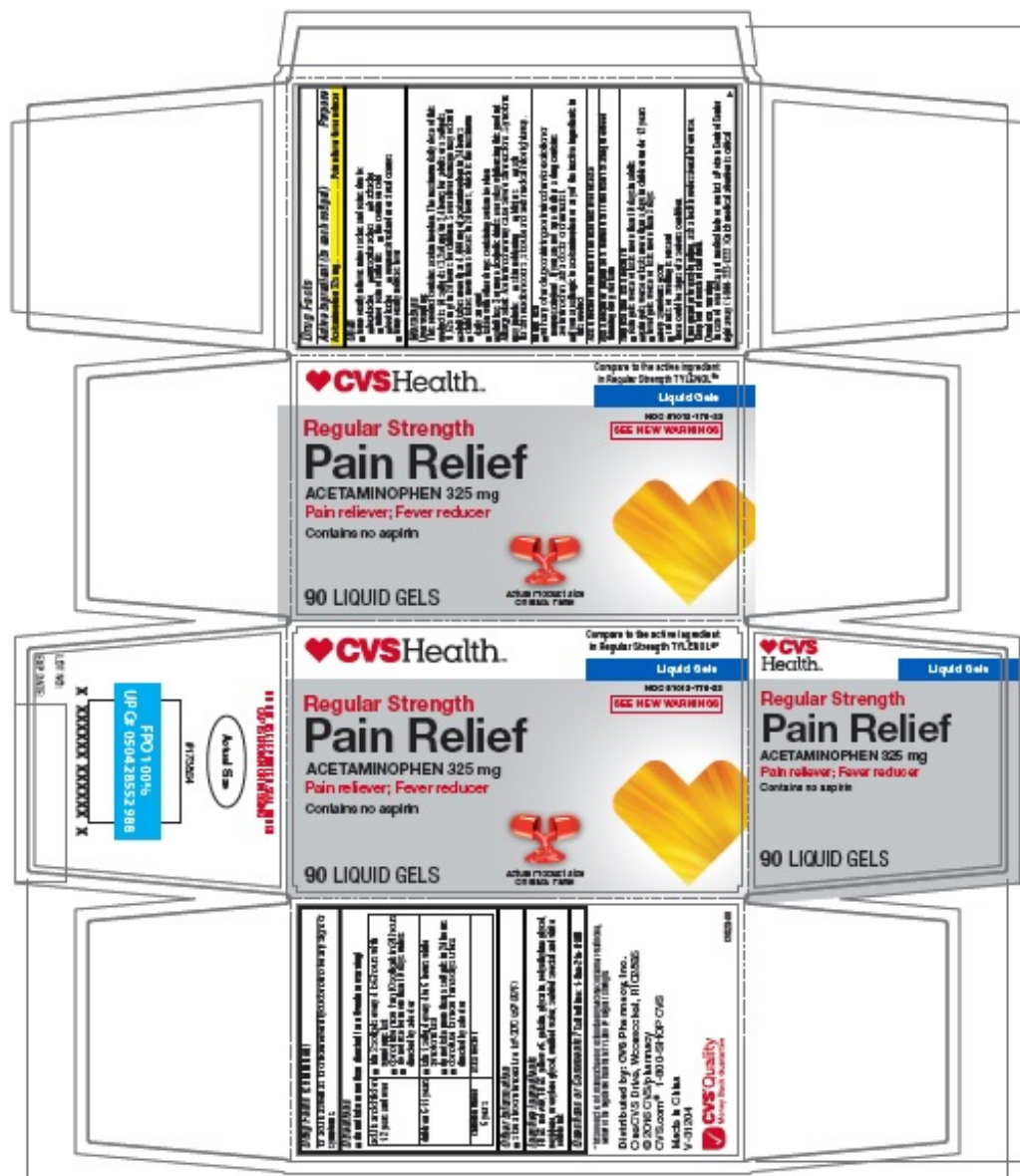
PRINCIPAL DISPLAY PANEL - 90ct Carton and Bottle Label

CVS Regular Strength Pain Relief

ACETAMINOPHEN 325 mg 90 LIQUID GELS

NDC 69842-075-23

*Compare to the active ingredient in **TYLENOL®** Regular Strength



REGULAR STRENGTH PAIN RELIEF

acetaminophen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-075
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 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)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	PC17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-075-15	1 in 1 CARTON	12/29/2016	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-075-23	1 in 1 CARTON	12/29/2016	
2		90 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/29/2016	

Labeler - CVS PHARMACY, INC. (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(69842-075) , analysis(69842-075)

Revised: 11/2019

CVS PHARMACY, INC.