

REGULAR STRENGTH PAIN RELIEF- acetaminophen capsule, gelatin coated
SPIRIT PHARMACEUTICALS LLC

VALUMEDS™ 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
- do not give this product to children for the pain of arthritis unless directed by a doctor

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 between 20-25°C (68-77°F)

Inactive ingredients

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

Questions or comments?

Call **1-888-333-9792**

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SPIRIT PHARMACEUTICALS LLC.**

RONKONKOMA, NY 11779

PRINCIPAL DISPLAY PANEL - 10 Softgel Bottle Carton

VALUMEDS™

**COMPARE to the active ingredient in
REGULAR STRENGTH TYLENOL®***

REGULAR STRENGTH

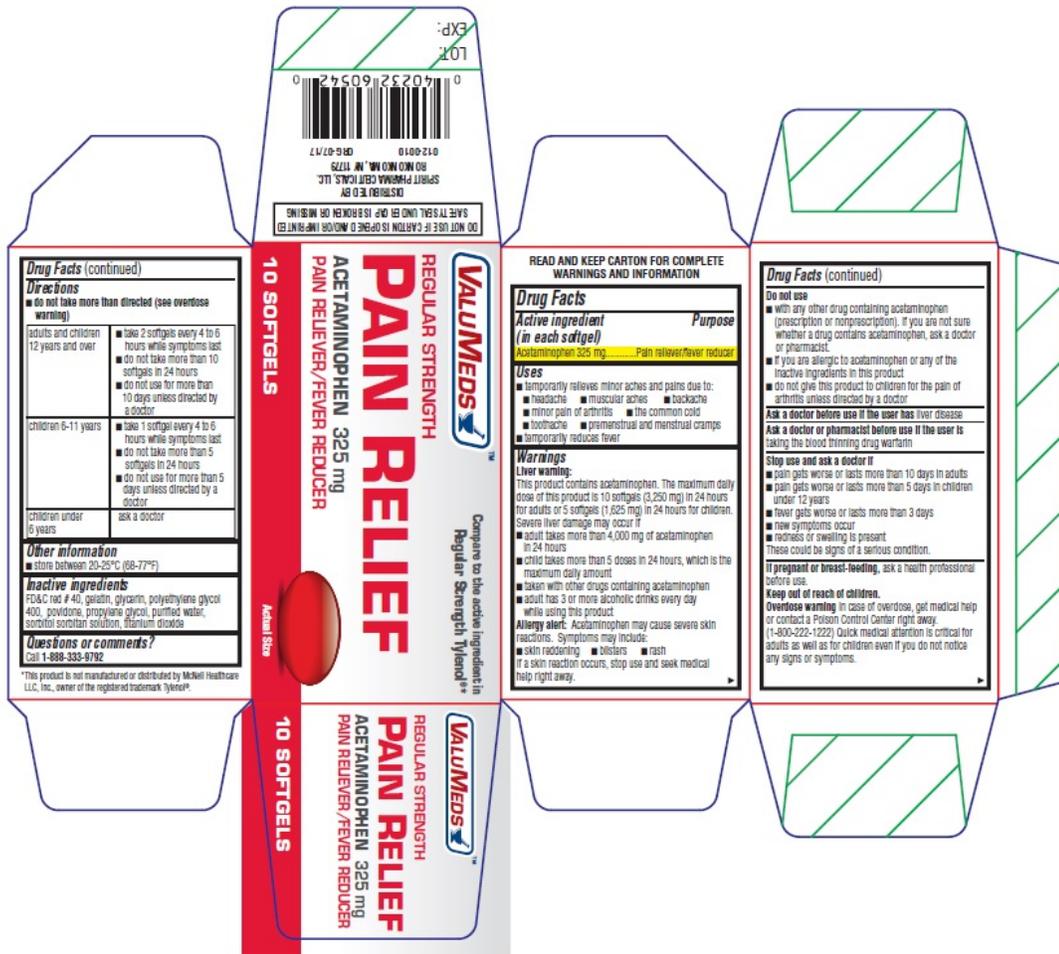
PAIN RELIEF

Acetaminophen 325 mg

PAIN RELIEVER/FEVER REDUCER

10 softgels

Actual Size



REGULAR STRENGTH PAIN RELIEF			
acetaminophen capsule, gelatin coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0120
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)				
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE K30 (UNII: U725QWY32X)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	red	Score	no score	
Shape	CAPSULE (OBLONG)	Size	21mm	
Flavor		Imprint Code	800	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0120-1	1 in 1 CARTON	04/10/2018	
1		10 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 Drug	M013	04/10/2018		

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)