

ASSURED REGULAR STRENGTH ACETAMINOPHEN- acetaminophen capsule, gelatin coated

SPIRIT PHARMACEUTICALS LLC

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.

ASSURED™ REGULAR STRENGTH ACETAMINOPHEN

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

**DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320**

PRINCIPAL DISPLAY PANEL - 10 Softgel Bottle Carton

ASSURED™

**COMPARE TO ACTIVE INGREDIENT IN
TYLENOL® REGULAR STRENGTH***

REGULAR STRENGTH

Acetaminophen

- **Acetaminophen 325 mg**
Pain Reliever / Fever Reducer

Actual Size

10 softgels



C639277337153

Drug Facts (continued)

Do not use

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READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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- hives
- skin rash
- skin blisters

If a skin reaction occurs, stop use and seek medical help right away.

EXP: LOT: 6 39277 33715 3

DISTRIBUTED BY GREENBERG NTEB NATIONAL, INC. 80 VOLVO PARKWAY, CHESTERFIELD, VA 23820 ORIG 04/16

DO NOT USE IF CARTON IS OPENED AND/OR IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

ASSURED[®]
REGULAR STRENGTH
Acetaminophen
• Acetaminophen 325 mg
Pain Reliever / Fever Reducer

COMPARE TO ACTIVE INGREDIENT IN
TYLENOL[®] REGULAR STRENGTH*



Actual Size

10 softgels

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REGULAR STRENGTH
Acetaminophen
• Acetaminophen 325 mg
Pain Reliever / Fever Reducer

Drug Facts (continued)

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*This product is not manufactured or distributed by McNeil Healthcare LLC, Inc., owner of the registered trademark Tylenol[®].

ASSURED REGULAR STRENGTH ACETAMINOPHEN acetaminophen capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0012	
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:68210-0012-1	1 in 1 CARTON	08/12/2016	
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 NOT FINAL	part343	08/12/2016		

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PVT LTD		872779008	MANUFACTURE(68210-0012)

