

**ACETAMINOPHEN- acetaminophen tablet**  
**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.*

-----

**VALUMEDS REGULAR STRENGTH PAIN RELIEF**

***Drug facts***

**Active ingredient (in each tablet)**

Acetaminophen 325 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. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. 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 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"><li>• take 2 tablets every 4 to 6 hours while symptoms last</li><li>• do not take more than 10 tablets in 24 hours, unless directed by a doctor</li><li>• do not use for more than 10 days unless directed by a doctor</li></ul>
children 6 years to under 12 years	<ul style="list-style-type: none"><li>• take 1 tablet every 4 to 6 hours while symptoms last</li><li>• do not take more than 5 tablets in 24 hours</li><li>• do not use for more than 5 days unless directed by a doctor</li></ul>
children under 6 years	ask a doctor

---

**Other information**

- store between 20-25°C (68-77°F)
- do not use if carton is opened or neck wrap or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing

**Inactive ingredients**

povidone, pregelatinized starch, sodium starch glycolate, stearic acid

**Questions or comments?**

**1-888-333-9792**

Distributed By

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

**PRINCIPAL DISPLAY PANEL - 40 COUNT BOTTLE CARTON**

**VALUMEDS™**

**Compare to the active ingredient in**

**Regular Strength Tylenol®\***

REGULAR STRENGTH

**PAIN RELIEF**

**ACETAMINOPHEN 325 mg**

PAIN RELIEVER/FEVER REDUCER

**40 TABLETS**

**ACTUAL SIZE**



# ACETAMINOPHEN

acetaminophen tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-0023
<b>Route of Administration</b>	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
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

**Product Characteristics**

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL340
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0023-1	1 in 1 CARTON	04/10/2018	
1		40 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	04/10/2018	

**Labeler** - SPIRIT PHARMACEUTICALS LLC (179621011)**Establishment**

Name	Address	ID/FEI	Business Operations
TIME-CAP LABS INC		037052099	manufacture(68210-0023)

Revised: 12/2019

SPIRIT PHARMACEUTICALS LLC