

ACETAMINOPHEN- acetaminophen tablet
SPIRIT PHARMACEUTICALS LLC

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"> • take 2 tablets every 4 to 6 hours while symptoms last • do not take more than 10 tablets in 24 hours, unless directed by a doctor • do not use for more than 10 days unless directed by a doctor
children 6 years to under 12 years	<ul style="list-style-type: none"> • take 1 tablet every 4 to 6 hours while symptoms last • do not take more than 5 tablets 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)

- 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 - 100 Tablets bottle

VALUMEDS

Compare to the active ingredient in

Regular Strength **Tylenol®***

REGULAR STRENGTH

PAIN

RELIEF

ACETAMINOPHEN 325 mg

PAIN RELIVER/

FEVER REDUCER

100 TABLETS

VALUMEDS
Compare to the active ingredient in Regular Strength Tylenol®**

REGULAR STRENGTH
PAIN RELIEF
ACETAMINOPHEN 325 mg
PAIN RELIEVER/
FEVER REDUCER

100 TABLETS

Drug Facts
Active ingredient (in each tablet) Purpose
Acetaminophen 325 mg.....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.

(continued under label)
Distributed By: Spirt Pharmaceuticals, LLC
Ronkonkoma, NY 11779 ORIG 04/17
ITEM# 101-01

0 40232 29125 8
Lot No.:
Exp. Date:
PREP HERE

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Drug Facts (continued)
Do not use
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 ■ take 2 tablets every 4 to 6 hours while symptoms last
12 years and over ■ do not take more than 10 tablets in 24 hours, unless directed by a doctor
do not use for more than 10 days unless directed by a doctor
children 6 years to ■ take 1 tablet every 4 to 6 hours while under 12 years symptoms last
children under ■ do not use for more than 5 days 6 years unless directed by a doctor
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
**This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Regular Strength Tylenol®

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0022
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
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:68210-0022-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/19/2017	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023

SPIRIT PHARMACEUTICALS LLC