ACETAMINOPHEN- acetaminophen tablet
Spirit Pharmaceuticals LLC

REGULAR STRENGTH PAIN RELIEVER

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 drugs 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	• 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	• 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

PRINCIPAL DISPLAY PANEL

SPRIIT 360

REGULAR STRENGTH

PAIN RELIEVER

ACETAMINOPHEN 325 mg

PAIN RELIEVER / FEVER REDUCER

100 TABLETS

ACETAMINOPHEN acetaminophen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-4125

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
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
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**	S31
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4125-0	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2021	
2	NDC:68210-4125-1	1 in 1 CARTON	04/06/2021	
2		100 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	04/06/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023 Spirit Pharmaceuticals LLC