

ACETAMINOPHEN- acetaminophen tablet
A-S Medication Solutions

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.

Acetaminophen Tablets, 325mg (uncoated)

Active Ingredient (in each tablet)/Purpose

Acetaminophen 325mg.....Analgesic/Antipyretic

Uses

temporary relief of minor aches and pains associated with

- common cold
- headache
- toothache
- muscular aches
- backache
- arthritis
- menstrual cramps
- and reduction of fever

Purpose

Analgesic/Antipyretic

Warnings

Alcohol warning:

If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do not use

with any other products containing acetaminophen.

Stop use and ask a doctor if

- symptoms do not improve
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- redness or swelling is present

- a rare sensitivity reaction occurs

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, contact a doctor or Poison Control Center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. **Do not exceed recommended dosage.**

Directions

Adults and children 12 years of age and older

- take 2 tablets every 4 to 6 hours as needed. Do not take more than 12 tablets in 24 hours.

Children 6-11 years of age

- Take 1 tablet every 4 to 6 hours as needed. Do not take more than 5 tablets in 24 hours.

Children under 6 years of age

- Do not use this regular strength product. This will provide more than the recommended dose (overdose) and could cause serious health problems.

Other Information

- store at room temperature 59°-86°F (15°-30°C).

Inactive Ingredients corn starch, pregelatinized starch, stearic acid.

May contain povidone and sodium starch glycolates.

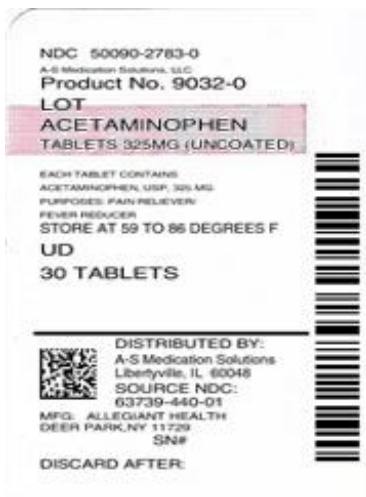
HOW SUPPLIED

Product: 50090-2783

NDC: 50090-2783-0 1 TABLET in a BLISTER PACK / 30 in a BOX, UNIT-DOSE

NDC: 50090-2783-1 30 TABLET in a BLISTER PACK / 25 in a BOX, UNIT-DOSE

Acetaminophen



ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-2783(NDC:63739-440)
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, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	AZ;010
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-2783-0	30 in 1 BOX, UNIT-DOSE	01/12/2017	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50090-2783-1	25 in 1 BOX, UNIT-DOSE	07/11/2017	

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30 in 1 BLISTER PACK; 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	03/01/2009	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-2783) , REPACK(50090-2783)

Revised: 3/2021

A-S Medication Solutions