PAIN RELIEF EXTRA STRENGTH- acetaminophen 500 mg tablet
Allegiant Health

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

temporary relief of minor aches and pains associated with ■ the common cold ■ headache ■ toothache ■ muscular aches ■ backache ■ minor pain from arthritis

■ premenstrual and menstrual cramps ■ temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take n more than 4,000mg
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
- 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 breastfeeding

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 (1-800-222-1222) right away.
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 use more than directed (see Overdose warning)**

Adults and children 12 years and over: take 2 caplets every 6 hours while symptoms last

Do not take more than 6 caplets in 24 hours, unless directed by a doctor

Do not use more than 10 days unless directed by a doctor

Children under 12 years: Consult a doctor

Other information

■ store between 20º-25ºC (68º-77ºF)
■ do not use if imprinted safety seal under cap is broken or missing

Inactive Ingredients

corn starch, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or Comments

Call 1-888-952-0050 Monday to Friday 9am-5pm EST

Package/Label Principal Display Panel

Health A2Z®

Compare to Tylenol® active ingredient*

See New Warnings Information

Extra Strength
PAIN RELIEF
Acetaminophen
Pain Reliever-Fever Reducer
CONTAINS NO ASPIRIN

500 mg

Pain Relief

PAIN RELIEF EXTRA STRENGTH

acetaminophen 500 mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69168-328
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics			
Color	white	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	AZ328
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69168-328-40	40 in 1 CARTON; Type 0: Not a Combination Product	12/17/2014	
2	NDC:69168-328-01	100 in 1 CARTON; Type 0: Not a Combination Product	12/17/2014	
3	NDC:69168-328-13	175 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2014	
4	NDC:69168-328-03	250 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2014	05/31/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/17/2014	

Labeler - Allegiant Health (079501930)

Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	analysis(69168-328) , label(69168-328) , manufacture(69168-328) , pack(69168-328)

Revised: 3/2020

Allegiant Health