ACETAMINOPHEN- acetaminophen tablet
Chain Drug Consortium,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.

Acetaminophen Tablets, USP 500 mg

Active ingredient

(in each tablet)

Acetaminophen, USP 500 mg

Purpose

Pain reliever/fever reducer

Uses

■ temporarily relieves minor aches and pains due to:

■ headache

■ muscular aches

■ backache

■ minor pain of arthritis

■ the common cold

■ toothache

■ premenstrual and menstrual cramps

■ temporarily reduces fever

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

■ 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 other 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 breast-feeding

ask a health professional before use

Keep out of the reach of children

Keep out of the 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 6 tablets in 24 hours

■ do not take more than 10 days unless directed by a doctor

children under 12 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 is broken or missing**

Inactive ingredients

hydroxypropyl cellulose, polyethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

call **1-844-724-7347** Mon-Fri 9:00 AM to 4:30 PM EST

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-657
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**
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G552
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68016-657-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2016	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph not final	part343	02/25/2016	

Labeler - Chain Drug Consortium,LLC (101668460)

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