# 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.

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# Acetaminophen Tablets, USP 325 mg

# **Active Ingredient**

(in each tablet)

Acetaminophen, USP 325 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

# **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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

#### 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

the user is 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
- do not take more than 10 days unless directed by a doctor children 6-11 years
- take 1 tablet every 4 to 6 hours while symptoms last
- do not take more than 5 tablets in 24 hours
- do not take more than 5 days unless directed by a doctor

children under 6 years

ask a doctor

#### Other information

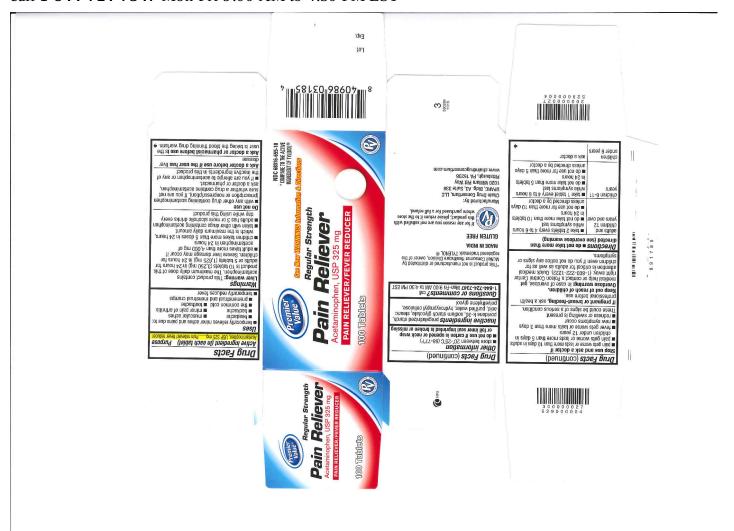
- store between 20-25°C (68-77°F).
- do not use if carton is opened or neck wrap or foil inner seal imprinted is broken or missing

# **Inactive ingredients**

hydroxy propyl cellulose, polyethylene glycol, povidone k-30, pregelatinized starch, purified water, 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:68016-655 Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PO VIDO NE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYDRO XYPRO PYL CELLULO SE, UNSPECIFIED (UNII: 9 XZ8 H6 N6 OH)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	G323	
Contains				

l	Packaging					
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
l	1 NDC:68016-655-10	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)

Revised: 3/2017 Chain Drug Consortium, LLC