PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet Chain Drug Marketing Association

1003-QCH-2024-0612

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 500 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. 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 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 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 6 hours while symptoms last do not take more than 6 tablets in 24 hours, unless directed by a doctor do not use for 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)
- retain carton for complete product information

Inactive ingredients

povidone, pregelatinized starch, sodium starch glycolate, stearic acid

PRINCIPAL DISPLAY PANEL

Quality Choice®

NDC 83324-081-01

†Compare to Active Ingredient in TYLENOL® Extra Strength

For Adults

Extra Strength

Pain Relief

Acetaminophen

Pain Reliever | Fever Reducer



PAIN RELIEF EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83324-081

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 500 mg

Inactive Ingredients Ingredient Name Strength POVIDONE (UNII: FZ989GH94E) STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ) SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics						
Color	white	Score	no score			
Shape	ROUND	Size	12mm			
Flavor		Imprint Code	M2A4;57344			
Contains						

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:83324- 081-01	1 in 1 CARTON	04/26/2024			
1		100 in 1 PACKAGE; Type 0: Not a Combination Product				
2	NDC:83324- 081-60	1 in 1 CARTON	04/26/2024			
2		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
3	NDC:83324- 081-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/12/2024			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	04/26/2024		

Labeler - Chain Drug Marketing Association (011920774)

Revised: 6/2024

Chain Drug Marketing Association