ACETAMINOPHEN- acetaminophen tablet Strategic Sourcing Services 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.

HMT - 1003 - 2018-1231

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

NDC 62011-0049-1

Health Mart®

compare to Tylenol® Extra Strength Tablets active ingredient †

extra strength

pain relief acetaminophen 500 mg pain reliever/fever reducer

contains no aspirin

for adults

100 tablets



ACETAMINOPHEN

acetaminophen tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0049	
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: FZ 989GH94E)			
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:62011- 0049-1	1 in 1 CARTON	12/13/2012	06/30/2024	
1		100 in 1 BOTTLE, PLASTIC; 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	12/13/2012	06/30/2024	

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 11/2022 Strategic Sourcing Services LLC