ACETAMINOPHEN- acetaminophen tablet Cardinal Health 107, LLC

5427-Major

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen 500 mg

ASPIRIN FREE

EXTRA STRENGTH PAIN RELIEVER

Purpose

Pain reliever/ Fever reducer

Uses

Temporarily reduces fever and relieves minor aches and pains due to:

- headache □
- muscular aches □
- backache □
- minor pain of arthritis □
- common cold □
- toothache □
- premenstrual and
- menstrual cramps

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.

- 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

Stop use and ask a doctor if \square

- 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 take for more than 10 days unless directed by a doctor

children under 12 years: ask a doctor

Other Information

store at room temperature

Povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?

Call (800) 616-2471

SAVE CARTON FOR COMPLETE DRUG FACTS

Do not use if carton is open or if imprinted safety seal under cap is broken or missing.

Distributed By:

Cardinal Health

Dublin, OH 43017

L5488143-10624

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol®

Principal Display Panel

ACETAMINOPHEN EXTRA STRENGTH TABLETS 500 mg 10 TABLETS



X117

NDC 55154-7897-0

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10 TABLETS

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STORAGE: Store in a dry place at 15° - 30° C (59° - 86° F).

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep out of reach of children.

DO NOT USE IF BLISTER UNIT IS TORN, BROKEN, OR SHOWS ANY SIGNS OF TAMPERING

Questions or comments? 1-800-231-4670

Distributed By: MAJOR® PHARMACEUTICALS Indianapolis, IN 46268 (800) 616-2471 www.majorpharmaceuticals.com

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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

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ACETAMINOPHEN

acetaminophen tablet

Product Information Product Type

Route of Administration

HUMAN OTC DRUG

ORAL

Item Code (Source)

NDC:55154-7897(NDC:0904-6730)

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 K30 (UNII: U725QWY32X)			
STARCH, CORN (UNII: O8232NY3SJ)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Product Characteristics					
Color	white	Score	2 pieces		
Shape	ROUND	Size	12mm		
Flavor		Imprint Code	54;27		
Contains					

P	Packaging						
#	tem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:55154- 7897-0	10 in 1 BAG	09/12/2018				
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	09/12/2018		

Labeler - Cardinal Health 107, LLC (118546603)

Revised: 6/2024 Cardinal Health 107, LLC