ACETAMINOPHEN- acetaminophen tablet
Cardinal Health, Inc.

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.

Leader Extra Strength Acetaminophen Tablets, 500 mg

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 500 mg

Purposes

Pain reliever/fever reducer

Uses

- for the temporary relief of minor aches and pains due to:
- headache
- the common cold
- backache
- minor pain of arthritis
- muscular aches
- toothache
- 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.

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)**
- a **dults 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

Inactive ingredients Povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or Comments? call **(800) 795-9775**

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

DISTRIBUTED BY

CARDINAL HEALTH

DUBLIN, OH 43017

www.myleader.com

1-800-200-6313

LEADER™

NDC 70000-0150-3

Extra Strength

Acetaminophen

Tablets, 500 mg

Pain Reliever / Fever Reducer

FOR ADULTS

Aspirin Free

225 TABLETS

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0150
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**
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND (round flat faced beveled edge)	**Size**	12mm
Flavor		**Imprint Code**	GPI;A5
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70000-0150-3	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/17/2016	04/30/2020

2	NDC:70000-0150-1	1 in 1 CARTON	01/16/2017	05/31/2021
2		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:70000-0150-2	1 in 1 CARTON	01/16/2017	06/30/2021
3		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	11/17/2016	06/30/2021

Labeler - Cardinal Health, Inc. (097537435)

Revised: 8/2018 Cardinal Health, Inc.