REGULAR STRENGTH ACETAMINOPHEN- acetaminophen tablet
Health Pharma USA 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.

Acetaminophen Regular Strength 325 mg

Active Ingredient

(in each tablet)

Acetaminophen 325mg

Purpose

Pain reliever/fever reducer

Uses

- temporary relieves minor aches and pains due to
- the common cold
- headache
- backache
- toothache
- muscular aches
- premenstrual and menstrual cramps and
- 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 have ever had an allergic reaction to this product or any of its ingredients

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: Taking more than the reccomended dose (overdose) may cause liver damage. In case of overdose. get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
Do not exceed recommended dosage.

Directions

- do not use more than directed **(see overdose warning)**
- Adults and children 12 years of age and older:
- Take 2 caplets every 6 hours while symptoms last.
- Do not take more than 6 caplets in 24 hours, unless directed by a doctor
- Do not use more than 10 days unless directed by a doctor.
- Children under 12 years of age: Do not use this extra strength product. This will provide more than the recommended dose (overdose) and could cause serious health problems.

Other Information

- store at controlled room temperature 20-25°C (68-77°F).
- read all product information before using.
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Inactive Ingredients

Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch, Polyethylene Glycol, Polyvinyl Pyrolidone, Stearic Acid, Talc, Titanium Dioxide

Questions or Comments

1-844-832-1138 (Mon-Fri 9AM-5PM EST) or www.healthlifeofusa.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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

Health Pharma USA LLC
1600 Hart Street, Rahway, NJ 07065
Phone: 732-540-8421

BULK LABEL _____of_____

PRODUCT NAME: Acetaminophen 325 mg Tablet		
PRODUCT CODE # PC076	**LOT #**	**Labeler code –** 71679-076-00
NET WEIGHT (KG)	**Caplets/BOX**	
16.00	**44,750 Tablet**	

WARNING: Keep out of Children. This bulk shipment is intended for further processing only. Repackage contents as soon as possible. This is a shipping container only and will not protect contents from damage by heat, cold and moisture indefinitely. Manufacturer will not accept responsibility for spoilage or violations of the food, Drug and cosmetic act due to prolonged storage in this container. Contents must be repackaged prior to resale and must be labeled in full compliance with the requirement of the Food, Drug and Cosmetic Act.
STORAGE: Store at a controlled room temperature 15-30°C (59-86° F)

REGULAR STRENGTH ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71679-076
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	APAP325
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-076-00	1 in 1 BOX	07/31/2017	
1		44750 in 1 BAG; 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	07/31/2017	

Labeler - Health Pharma USA LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	manufacture(71679-076)

Revised: 9/2019 Health Pharma USA LLC