EXTRA STRENGHTH ACETAMINOPHEN- acetaminophen tablet
HealthLife of USA

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 Extra Strength 500 mg

Active Ingredient

(in each tablet)

Acetaminophen 500mg

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

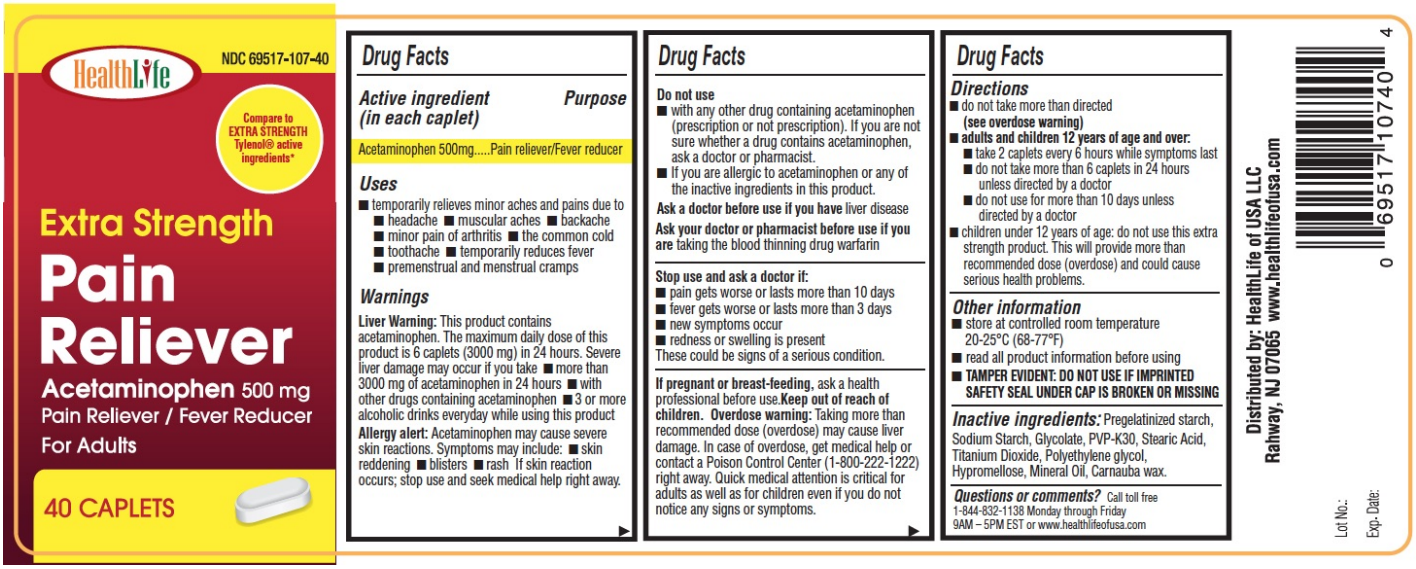
Questions or Comments

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*.

NDC 69517-107-40 40 Caplets



EXTRA STRENGHTH ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69517-107
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**
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	white	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	BH
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-107-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2017	
2	NDC:69517-107-40	1 in 1 CARTON	07/31/2017	
2		40 in 1 BOTTLE; 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 - HealthLife of USA (079656178)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceutical Ltd.		915664486	manufacture(69517-107)

Revised: 4/2020 HealthLife of USA