

TYLENOL EXTRA STRENGTH CAPLET- acetaminophen tablet
Jones Healthcare Group - Packaging Services, Inc

Tylenol Extra Strength

Active ingredient (in each caplet)

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

This product contains acetaminophen. Severe liver damage may occur if you take • more than 4,000 mg of acetaminophen in 24 hours **Liver warning:**

- 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 warnings:

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:	<ul style="list-style-type: none">• take 2 capletes every 6 hours while symptoms last• do not take more than 6 capletes 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 20-25C (68-77F)
- **do not use if pouch is torn or damaged.**

Inactive ingredients

carnauba wax*, corn starch*, FD&C red no.40 aluminum lake, hypromellose, magnesium stearate, modified starch*, polyethylene glycol*, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide * contains one or more of these ingredients

Questions or comments?

Call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

Package Labeling:

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 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 for more than 10 days unless directed by a doctor Children under 12 years: ask a doctor

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To Open: While Folded on Line, Tear At Slit

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

TYLENOL®
FOR ADULTS

Acetaminophen Pain Reliever-Fever Reducer

Extra Strength 2 Caplets
500 mg each

Active ingredient (in each caplet)

Acetaminophen 500 mg.....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

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TYLENOL EXTRA STRENGTH CAPLET

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67414-449
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDWL1A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	TYLENOL500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67414-449-00	2500 in 1 BOX	01/24/2018	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67414-449-10	50 in 1 BOX	01/24/2018	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:67414-449-11	50 in 1 BOX	01/24/2018	
3		2 in 1 POUCH; 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	01/24/2018	

Labeler - Jones Healthcare Group - Packaging Services, Inc (243261024)

Registrant - Jones Healthcare Group - Packaging Services, Inc (243261024)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Louisiana, LLC		830397282	manufacture(67414-449)

Establishment

Name	Address	ID/FEI	Business Operations
McNeil Healthcare LLC.		831188763	manufacture(67414-449)

Revised: 11/2023

Jones Healthcare Group - Packaging Services, Inc