TYLENOL EXTRA STRENGTH CAPLET- acetaminophen tablet
Jones Contract Packaging Services

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.

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 menstual cramps • temporarily reduces lever

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.

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:	• 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 ***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)

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McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA ©J&JCI 2016 30035005

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)	*Purpose*
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

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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: 3WJQ0SDW1A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
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 not final	part343	01/24/2018	

Labeler - Jones Contract Packaging Services (243697187)

Registrant - Jones Contract Packaging Services (243697187)

Establishment

Name	Address	ID/FEI	Business Operations
Jones Contract Packaging Services		243697187	pack(67414-449)

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)