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# 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

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> <li>take 2 capletes every 6 hours while symptoms last</li> <li>do not take more than 6 capletes in 24 hours, unless directed by a doctor</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
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 **m** pain gets worse or lasts more than 10 days 🔳 fever gets worse or lasts more than 3 days 🔳 new symptoms occur to days milerer gets worse or lasts mote cutor beings of a serious condition. miredness 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 provide the series of the series 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 a do not take more than directed (see overdose warning). Adults and children 12 years and over: m take 2 caplets every 6 hours while symptoms last a 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 a store between 20-25C (68-77F) a 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) Distributed by: JOHNSON & JOHNSON CONSUMER INC.

30035005

McNeil Consumer Healthcare Division

Fort Washington, PA 19034 USA ©J&JCI 2016

FOR ADULTS Acetaminophen Pain Reliever-Fever Reducer 2 Caplets Extra Strength 500 mg each Purpose Active ingredient (in each caplet)

To Open: While Folded on Line, Tear At Slit

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

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 m 3 or more alcoholic drinks every day while using this product. Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: m skin reddening m blisters mrash If a skin reaction occurs, stop use and seek medical help right away. Bus en use more may be dress much any after during and service severe skin in a skin reaction occurs, stop use and seek medical help right away.

Do not use with any other drug containing acetaminophen (prescription

To Open: While Folded on Line, Tear At Slit

or nonprescription). If you are not sure whether a drug contains acetaminopher ask a doctor or pharmacist. If you are allergic to acetaminophen, 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 warlarin. Stop use and ask a doctor if **m** pain gets worse or lasts more than 10 days = lever gets worse or lasts more than 3 days = new symptoms occur u days an ever gets worse of rasis more than 3 days a new symptoms uccur aredness 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 il 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: a take 2 caplets every 6 hours while symptoms last a 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 m store between 20-25C (68-77F) m 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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R FOR ADULTS Acetaminophen Pain Reliever-Fever Reducer 2 Caplets Extra Strength 500 mg each Purpose Active ingredient (in each caplet) Uses temporarily relieves minor aches and pains due to: The common cold is the adache is backache is minor pain of arthritis is othache is muscular aches is premenstrual and menstrual cramps temporarily reduces lever
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Denne use myth any other drug englishing acetaminophen in generation.

Do not use **u** with any other drug containing acetaminophen (prescription



TYLENOL EXTRA ST	RENGTH CAPLE	T			
acetaminophen tablet					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (So	urce)	NDC:674	14-449
Route of Administration	ORAL				
Active Ingredient/Active	e Moiety				
Ing	redient Name		Basis of St	rength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN					
ACETAMINOPHEN (UNII: 36209)	FL9D) (ACETAMINOPHEN - UN	II:362O9ITL9D)	ACETAMINOPH	EN	500 mg
Inactive Ingredients		II:362O9ITL9D)	ACETAMINOPH		-
Inactive Ingredients	Ingredient Name	II:362O9ITL9D)	ACETAMINOPH		500 mg trength
Inactive Ingredients CARNAUBA WAX (UNII: R12CBM0	Ingredient Name	II:362O9ITL9D)	ACETAMINOPH		-
Inactive Ingredients CARNAUBA WAX (UNII: R12CBM0 STARCH, CORN (UNII: 08232NY3	Ingredient Name EIZ) SJ)	II:362O9ITL9D)	ACETAMINOPH		-
Inactive Ingredients CARNAUBA WAX (UNII: R12CBMC STARCH, CORN (UNII: 08232NY3 FD&C RED NO. 40 (UNII: WZ B91	<b>Ingredient Name</b> EIZ) SJ) 27XOA)	II:362O9ITL9D)	ACETAMINOPH		-
Inactive Ingredients CARNAUBA WAX (UNII: R12CBM0 STARCH, CORN (UNII: 08232NY3 FD&C RED NO. 40 (UNII: WZ B91 ALUMINUM OXIDE (UNII: LMI260	Ingredient Name EIZ) SJ) 27XOA) 6933)	II: 362O9ITL9D)	ACETAMINOPH		-
Inactive Ingredients CARNAUBA WAX (UNII: R12CBMC STARCH, CORN (UNII: 08232NY3 FD&C RED NO. 40 (UNII: WZ B91 ALUMINUM OXIDE (UNII: LMI260 HYPROMELLOSE, UNSPECIFIED	Ingredient Name EIZ) SJ) 27XOA) 6933) 0 (UNII: 3NXW29V3WO)	II: 362O9ITL9D)	ACETAMINOPH		-
Inactive Ingredients CARNAUBA WAX (UNII: R12CBM0 STARCH, CORN (UNII: 08232NY3 FD&C RED NO. 40 (UNII: WZ B91 ALUMINUM OXIDE (UNII: LMI260 HYPROMELLOSE, UNSPECIFIEL MAGNESIUM STEARATE (UNII: 7	Ingredient Name EIZ) SJ) 27XOA) 6933) (UNII: 3NXW29V3WO) 0097M6I30)		ACETAMINOPH		-
Inactive Ingredients CARNAUBA WAX (UNII: R12CBMC STARCH, CORN (UNII: 08232NY3 FD&C RED NO. 40 (UNII: WZ B91 ALUMINUM OXIDE (UNII: LMI260 HYPROMELLOSE, UNSPECIFIEI MAGNESIUM STEARATE (UNII: 7 POLYETHYLENE GLYCOL, UNSI	Ingredient Name EIZ) SJ) 27XOA) 6933) 0 (UNII: 3NXW29V3WO) 0097M6I30) PECIFIED (UNII: 3WJQ0SDWL		ACETAMINOPH		-
Inactive Ingredients CARNAUBA WAX (UNII: R12CBMC STARCH, CORN (UNII: 08232NY3 FD&C RED NO. 40 (UNII: WZ B91 ALUMINUM OXIDE (UNII: LMI260 HYPROMELLOSE, UNSPECIFIED MAGNESIUM STEARATE (UNII: 7 POLYETHYLENE GLYCOL, UNSI POWDERED CELLULOSE (UNII:	Ingredient Name EIZ) SJ) 27XOA) 6933) • (UNII: 3NXW29V3WO) 0097M6I30) • CIFIED (UNII: 3WJQ0SDW1. 5MD1X3XO9M)		ACETAMINOPH		-
Inactive Ingredients CARNAUBA WAX (UNII: R12CBMC STARCH, CORN (UNII: 08232NY3 FD&C RED NO. 40 (UNII: WZ B91 ALUMINUM OXIDE (UNII: LMI260 HYPROMELLOSE, UNSPECIFIED MAGNESIUM STEARATE (UNII: 7 POLYETHYLENE GLYCOL, UNSI	Ingredient Name EIZ) SJ) 27XOA) 6933) • (UNII: 3NXW29V3WO) 0097M6I30) • CIFIED (UNII: 3WJQ0SDW1. 5MD1X3XO9M)		ACETAMINOPH		-

2	roduct Chara	cteristics					
C	olor	white	Score			no score	
Shape		OVAL	Size	Size		18mm	
Flavor			Imprint Code	Imprint Code		TYLENOL500	
С	ontains						
P	ackaging						
#	ltem Code	Package	e Description	ľ	Marketing S Date	tart	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/	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 Product	0: Not a Combination				
Μ	larketing l	nformation					
	Marketing Category	Application	Number or Monogra Citation	ph	Marketing Date		Marketing End Date
	TC 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	<b>Business Operations</b>			
Dr. Reddy's Laboratories Louisiana, LLC		830397282	manufacture(67414-449)			

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

Revised: 11/2023

Jones Healthcare Group - Packaging Services, Inc