EXTRA STRENGTH PAIN RELIEVER- acetaminophen 500 mg tablet
Lil' Drug Store Products, Inc.

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.

Extra Strength Pain Reliever

Drug facts

Active Ingredient (in each tablet)

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

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 6 tablets (3,000 mg) in 24 hours.

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 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 recommended 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.

Directions
- **do not take more than directed (see overdose warning)**

adults and children 12 years and over	◦ take 2 tablets every 6 hours while symptoms last ◦ do not take more than 6 tablets 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

- **do not use if inner pouch or carton is open or damaged**
- store at room temperature 59-86˚F (15-30˚C)
- see bottom panel for lot number and expiration date

Inactive Ingredients

corn starch, hypromellose, maltodextrin [1] , microcrystalline cellulose [1] , polyethylene glycol, povidone [1] , pregelatinized starch [1] , sodium starch glycolate [1] , stearic acid, titanium dioxide [1]

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1 may contain

Questions or Comments?

call toll-free **1-800-351-2000 (M-F 8:00 AM-4:30 PM CST)**

*This product is not manufactured or distributed by JOHNSON & JOHNSON, INC., McNeil Consumer Healthcare Division,

distributor of Tylenol® Extra Strength.

Manufactured for:

Lil' Drug Store products, Inc.

9300 Earhart Lane SW

Cedar Rapids, IA 52404

COMPARE TO THE ACTIVE INGREDIENT IN

Tylenol® Extra Strength*

Extra Strength

Pain Reliever

Acetaminophen 500mg

Pain Reliever/Fever Reducer

actual size [pill image]

2 TABLETS PER POUCH

EXTRA STRENGTH PAIN RELIEVER

acetaminophen 500 mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:29485-9281
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, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	AZ;235
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485-9281-3	30 in 1 BOX	01/17/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:29485-9281-2	25 in 1 BOX	01/17/2017	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:29485-9281-4	50 in 1 BOX	01/17/2017	
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 final	M013	01/17/2017	

Labeler - Lil' Drug Store Products, Inc. (093103646)