# PAIN RELIEVER EXTRA STRENGTH- acetaminophen tablet, film coated Walgreen Company

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.

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#### **Pain Reliever**

## Active ingredient (in each caplet)

Acetaminophen 500 mg

#### Purpose

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - the common cold
  - 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

If a skin reaction occurs, stop use and seek medical help right away.

#### Do not use

- if you are allergic to acetaminophen or any of the inactive ingredients in this product
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

## 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
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

## If pregnant of breast-feeding,

ask a health professional before use.

## Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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
- 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 take for more than 10 days unless directed by a doctor
- children under 12 years: ask a doctor

### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

#### **Inactive ingredients**

castor oil, hypromellose, povidone, sodium starch glycolate, starch, stearic acid

#### Questions or comments?

1-800-426-9391

### **Principal Display Panel**

#### **Walgreens**

Compare to Tylenol® Extra Strength Caplets active ingredient††

NDC 0363-0175-08

#### **Pain Reliever**

ACETAMINOPHEN 500 mg / PAIN RELIEVER / FEVER REDUCER

EXTRA STRENGTH CAPLETS

#### **24** CAPLETS

**ACTUAL SIZE** 

## TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

PHARMACIST *Walgreens* Trusted since  $1901^{\text{TM}}$  RECOMMENDED† Health expertise you rely on TM.

†Walgreens Pharmacist Survey

††This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol<sup>®</sup> Extra Strength Caplets.

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Walgreens 44-175

## PAIN RELIEVER EXTRA STRENGTH

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acetaminophen tablet, film coated					
<b>Product Information</b>					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:0363-	0 175
Route of Administration	ORAL				
Active Ingredient/Active Mei	\ <b>4.</b> ,				
Active Ingredient/Active Moiety					
In	gredient Name		Basis of	Strength	Strength

Inactive Ingredients					
Ingredient Name	Strength				
HYPROMELLOSES (UNII: 3NXW29 V3WO)					
PO VIDONE (UNII: FZ989GH94E)					
STEARIC ACID (UNII: 4ELV7Z65AP)					
CASTOR OIL (UNII: D5340 Y2I9 G)					

Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	44;175	
Contains				

Packaging					
#	Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:0363-0175- 12	1 in 1 CARTON	04/02/1993		
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:0363-0175- 08	1 in 1 CARTON	04/02/1993		
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
3	NDC:0363-0175- 15	1 in 1 CARTON	04/02/1993		
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
4	NDC:0363-0175- 99	1 in 1 CARTON	04/02/1993		
4		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
5	NDC:0363-0175- 20	1 in 1 CARTON	04/02/1993		
5		225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
6	NDC:0363-0175- 37	1 in 1 CARTON	04/02/1993	02/07/2021	
6		75 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
7	NDC:0363-0175- 57	1 in 1 CARTON	04/02/1993	02/07/2021	
7		125 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
8	NDC:0363-0175- 03	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/1993		
9	NDC:0363-0175- 14	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/1993	07/08/2018	
10	NDC:0363-0175- 29	150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/1993		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	<b>Marketing Start Date</b>	Marketing End Date			
OTC MONOGRAPH NOT FINAL	part343	04/02/1993				

## Labeler - Walgreen Company (008965063)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		038154464	PACK(0363-0175)		

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(0363-0175), PACK(0363-0175)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	PACK(0363-0175)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0363-0175)

Revised: 1/2020 Walgreen Company