# PAIN RELIEF EXTRA STRENGTH- acetaminophen capsule, coated Publix Super Markets 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.

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## Publix Super Markets, Inc. Pain Relief Drug Facts

## **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**

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (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

## 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 have ever had an allergic reaction to this product or any of its ingredients

## 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.

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 Liver warning)

adults and children 12 years and over	<ul> <li>take 2 caplets every 6 hours while symptoms last</li> <li>do not take more than 6 caplets 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 at 20°-25°C (68°-77°F)

## **Inactive ingredients**

hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

## **Principal Display Panel**

**EXTRA STRENGTH** 

painrelief

**ACETAMINOPHEN 500mg** 

PAIN RELIEVER/FEVER REDUCER

easy to swallow caplets

for adults

**ACTUAL SIZE** 

Compare to Active Ingredient in Extra Strength Tylenol® Caplets



# EXTRA STRENGTH

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

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**Inactive ingredients** hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

\*This product is not manufactured or distributed by McNeil Healthcare LLC, distributor of Extra Strength Tylenol® Caplets.

Made in India

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## PUBLIX GUARANTEE:

COMPLETE SATISFACTION OR YOUR MONEY BACK



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LOT NO.

EXP.

: 91778 63 C3

## PAIN RELIEF EXTRA STRENGTH

acetaminophen capsule, coated

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:56062-917	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	500 mg	

Inactive Ingredients				
Ingredient Name	Strength			
HYPROMELLOSES				
POLYETHYLENE GLYCOLS				
POVIDONES				
STEARIC ACID				

Product Characteristics				
Color	WHITE	Score	no score	
Shape	CAPSULE	Size	16 mm	
Flavor		Imprint Code	L917	
Contains				

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date

1	NDC:56062-917-71	1 in 1 CARTON	
1		50 in 1 BOTTLE	
2	NDC:56062-917-78	1 in 1 CARTON	
2		100 in 1 BOTTLE	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	0 1/3 1/2 0 11		

# Labeler - Publix Super Markets Inc (006922009)

## Registrant - L. Perrigo Company (006013346)

Revised: 2/2013 Publix Super Markets Inc