# EXTRA STRENGTH ASPIRIN FREE PAIN RELIEF- acetaminophen capsule Safeway

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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**Safeway 44-445** 

#### Active ingredients (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 pains of arthritis
  - toothache
  - muscular aches
  - premenstrual and menstrual cramps
- temporarily reduces fever

#### Warnings

**Liver warnings**: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 caplets in 24 hours, which is the maximum daily amount
- 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.

#### 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 befure 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 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 caplets every 4 to 6 hours while symptoms last
  - swallow whole do not crush, chew or dissolve
  - do not take more than 8 caplets in 24 hours
  - do not take for more than 10 days unless directed by a doctor
- children under 12 years: doi not use this adult extra strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage.

#### Other information

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

#### **Inactive ingredients**

corn starch, flavor, polyethylene glycol, polyvinyl alcohol, povidone, sodium starch glycolate\*, stearic acid, sucralose, talc, titanium dioxide

#### Questions or comments?

1-800-426-9391

#### Principal display panel

NDC 21130-445-15

Compare to Tylenol® Extra Strength Cool Caplets active ingredient†

Extra Strength

**Aspirin Free Pain Relief Acetaminophen**, 500 mg

- Cool Caplets
- · Pain Reliever
- Fever Reducer

**50** CAPLETS, 500 mg EACH

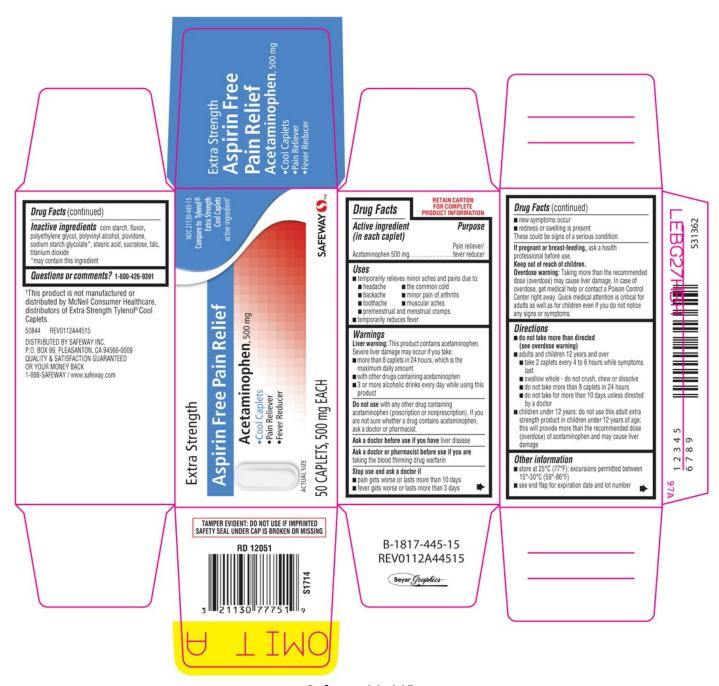
#### **SAFEWAY**<sub>TM</sub>

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributors of

<sup>\*</sup>may contain this ingredient

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



**Safeway 44-445** 

# EXTRA STRENGTH ASPIRIN FREE PAIN RELIEF acetaminophen capsule Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:21130-445 Route of Administration ORAL DEA Schedule

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

Inactive Ingredients				
Ingredient Name	Strength			
SUCRALOSE				
TALC				
TITANIUM DIO XIDE				

Product Characteristics			
Color	WHITE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	44;445
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-445-15	1 in 1 CARTON		
1		50 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	02/10/2005	

### **Labeler -** Safeway (009137209)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		038154464	PACK(21130-445)	

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	MANUFACTURE(21130-445)	

Revised: 10/2012 Safeway