

## **PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet**

### **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 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. 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 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.**

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 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 style="list-style-type: none"><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**

carnauba wax, corn starch\*, croscarmellose sodium\*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid

\*may contain one or more of these ingredients

**Questions or comments?**

1-888-723-3929

**Principal Display Panel**

Extra Strength

Compare to Extra Strength Tylenol® Caplets active ingredient

Pain Relief

Acetaminophen Caplets 500 mg

Pain Reliever

Fever Reducer

For Adults

ACTUAL SIZE

SEE NEW WARNINGS

24 CAPLETS



Extra Strength

# Pain Relief

Acetaminophen Caplets 500 mg

- Pain Reliever • Fever Reducer
- For Adults

ACTUAL SIZE SEE NEW WARNINGS

24 CAPLETS

**SAFEMAY** 



NDC 21130-484-62

Compare to  
Extra Strength  
Tylenol® Caplets  
active ingredient\*\*

OUR PROMISE

100% GUARANTEED

OR YOUR MONEY BACK

QUALITY & SATISFACTION

1-888-SAFEMAY/ www.safeway.com

DISTRIBUTED BY SAFEMAY, INC.  
P.O. BOX 99, PEASANTON, CA 94566-0099

distributed by McNeil Consumer Healthcare,  
distributor of Extra Strength Tylenol® Caplets.

\*\*This product is not manufactured or  
distributed by McNeil Consumer Healthcare.

CONTAINS NO ASPIRIN

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

**Drug Facts (continued)**

**Do not use** 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**

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: 48462 15 C10

**Drug Facts (continued)**

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<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (caplet)	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	L484
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-484-62	1 in 1 CARTON		
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21130-484-78	1 in 1 CARTON		
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:21130-484-85	1 in 1 CARTON		
3		250 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:21130-484-90	500 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:21130-484-76	1 in 1 CARTON		
5		120 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:21130-484-71	1 in 1 CARTON		
6		50 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:21130-484-02	550 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/06/2000	

