

**PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet  
Family Dollar (FAMILY WELLNESS)**

*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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**Drug Facts**

**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 a 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 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. 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 6 hours while symptoms last
  - do not take more than 6 caplets in 24 hours
  - do not take for more than 10 days unless directed by a doctor
- children under 12 years: do not use

### **Other information**

- store between 20-25°C (68-77°F)

### **Inactive ingredients**

corn starch, croscarmellose sodium\*, hypromellose\*, lactose monohydrate\*, magnesium stearate\*, maltodextrin\*, medium-chain triglycerides\*, mineral oil\*, polydextrose\*, polyethylene glycol\*, polyvinyl alcohol\*, povidone, purified water\*, sodium starch glycolate, stearic acid\*, talc\*, titanium dioxide

\*contains one or more of these ingredients

## **Questions or comments?**

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

## **Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENT OF **TYLENOL® EXTRA STRENGTH†**

EXTRA STRENGTH

### **Acetaminophen**

Pain Reliever Fever Reducer

CAPLETS

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Extra Strength.

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

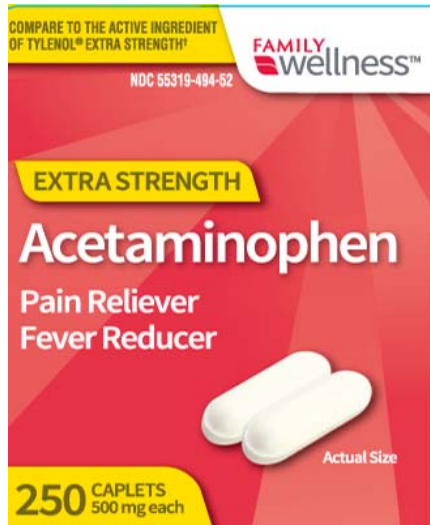
**DISTRIBUTED BY:**

**MIDWOOD BRANDS, LLC**

**10611 MONROE RD.**

**MATTHEWS, NC 28105**

**Product Label**



**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

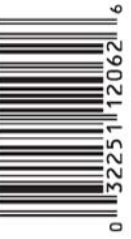
<b>Drug Facts</b>
<b>Active ingredient (in each caplet)</b> Acetaminophen 500 mg Pain reliever/fever reducer
<b>Uses</b> <ul style="list-style-type: none"> <li>Temporarily relieves minor aches and pains due to <ul style="list-style-type: none"> <li>headache</li> <li>backache</li> <li>toothache</li> <li>premenstrual and menstrual cramps</li> </ul> </li> <li>the common cold</li> <li>minor pain of arthritis</li> <li>muscular aches</li> <li>temporarily reduces fever</li> </ul>
<b>Warnings</b> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> <li>more than 4,000 mg of acetaminophen in 24 hours</li> <li>with other drugs containing acetaminophen</li> <li>3 or more alcoholic drinks every day while using this product</li> </ul> <p><b>Alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> <li>skin redness</li> <li>skin rash</li> <li>skin peeling</li> <li>skin blisters</li> <li>itching</li> </ul> <p>If a skin reaction occurs, stop use and seek medical help right away.</p>

**Drug Facts (continued under label)**

This product is not manufactured or distributed by McKel Consumer Healthcare, distributor of Tylenol® Extra Strength.

**DISTRIBUTED BY: MIDWOOD BRANDS, LLC**  
10611 MONROE RD., MATTHEWS, NC 28105

**NOT 100% SATISFIED?**  
Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.



Lot No.: P.D.-A1080 L8006044 Exp. Date:



<b>Drug Facts (continued)</b>
<b>Do not use</b> <ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>if you are allergic to acetaminophen or any of the inactive ingredients in this product.</li> </ul>
<b>Ask a doctor before use if you have liver disease.</b>
<b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b>
<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>fever gets worse or lasts more than 10 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>new symptoms occur</li> <li>redness or swelling is present</li> </ul> <p>These could be signs of a serious condition.</p>
<b>If pregnant or breast-feeding, ask a health professional before use.</b>
<b>Keep out of reach of children.</b>
<b>Overdose warning:</b> 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.
<b>Directions</b> <ul style="list-style-type: none"> <li>do not take more than directed (see Overdose warning)</li> <li>adults and children 12 years and over</li> <li>take 2 caplets every 6 hours while symptoms last</li> <li>do not take more than 6 caplets in 24 hours</li> <li>do not take for more than 10 days unless directed by a doctor</li> <li>children under 12 years do not use</li> </ul>
<b>Other information</b> <ul style="list-style-type: none"> <li>store between 20-25°C (68-77°F)</li> </ul>
<b>Inactive ingredients</b> corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, methylcellulose, medium-chain triglycerides, mineral oil, polyethylene glycol, polyvinyl alcohol, polydioxane, purified water, sodium starch glycolate, stearic acid, talc, titanium dioxide, contains one or more of these ingredients
<b>Questions or comments?</b> Call 1-877-353-3633 Monday-Friday 9AM-5PM EST

**FAMILY WELLNESS Extra Strength Acetaminophen**

<b>PAIN RELIEF EXTRA STRENGTH</b>			
acetaminophen tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-494
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	STARCH, CORN (UNII: O8232NY3S)		
	CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
	HYPROMELLOSES (UNII: 3NXW29V3WO)		
	LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
	MAGNESIUM STEARATE (UNII: 70097M6130)		

<b>MINERAL OIL</b> (UNII: T5L8T28FGP)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)
<b>POVIDONE</b> (UNII: FZ989GH94E)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL341;AV;0821;P500
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-494-25	1 in 1 BOX	03/31/2016	04/26/2024
1		250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:55319-494-50	1 in 1 BOX	03/31/2016	04/26/2024
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:55319-494-00	1 in 1 BOX	03/31/2016	04/26/2024
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:55319-494-52	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2016	04/26/2024

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/31/2016	04/26/2024

**Labeler** - Family Dollar (FAMILY WELLNESS) (024472631)