

**ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet**  
**Family Dollar Stores, LLC**

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**Drug Facts**

**Active ingredient (in each gelcap)**

Acetaminophen USP 500 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - backache
  - minor pain of arthritis
  - the common cold
  - toothache
  - 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 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. (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 gelcaps every 6 hours while symptoms last</li> <li>• do not take more than 6 gelcaps 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 between 20° to 25°C (68° to 77°F). Avoid high humidity

- **do not use if carton is open. Do not use if printed foil seal under cap is torn or missing**

### **Inactive ingredients**

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, FD&C blue #1, FD&C red #3, FD&C red #40, gelatin, hydroxypropyl cellulose, magnesium stearate, polyethylene glycol, pregelatinized starch (maize), propylene glycol, shellac glaze, sodium starch glycolate, talc and titanium dioxide.

### **Questions or comments?**

**1-855-274-4122**

**DISTRIBUTED BY: MIDWOOD BRANDS, LLC**  
500 VOLVO PKWY, CHESAPEAKE, VA 23320 USA  
**Made in India**

Code: TS/DRUGS/16/2014

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (100 Gelcaps Container Label)**

**FAMILY**  
**Wellness™**

**EXTRA STRENGTH**  
**PAIN RELIEF**  
**Acetaminophen Gelcaps**  
**500 mg**  
**Pain Reliever, Fever Reducer**  
**Rapid Release Gels**

**FOR ADULTS**

**100 GELCAPS**  
**500 mg Each**

**NDC 55319-053-21**



EXTRA STRENGTH  
**PAIN RELIEF**

Acetaminophen Gelscaps  
500 mg

Pain Reliever, Fever Reducer

Rapid Release Gels

FOR ADULTS

**100 GELCAPS**  
500 mg Each NDC 55319-053-21

**Important:** Read all product information before using.  
**DO NOT USE IF PRINTED FOIL SEAL UNDER CAP IS TORN OR MISSING**  
**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

**Drug Facts**

**Active ingredient (in each gelscap)**  
Acetaminophen USP 500 mg

**Purpose**  
Pain reliever/fever reducer

**Uses**  
temporarily relieves minor aches and pains due to:  
headache ■ muscular aches ■ backache ■ minor pain of arthritis  
the common cold ■ toothache ■ 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 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 (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 ■ take 2 gelscaps every 6 hours while symptoms last ■ do not take more than 6 gelscaps in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor, children under 12 years: ask a doctor

**Other information**  
store between 20° to 25°C (68° to 77°F). Avoid high humidity  
do not use if printed foil seal under cap is torn or missing.  
**Inactive ingredients:** ammonium hydroxide, black iron oxide, colloidal silicon dioxide, FD&C blue #1, FD&C red #40, gelatin, hydroxypropyl cellulose, magnesium stearate, polyethylene glycol, polyethylene glycol succinate, polyethylene glycol, shellac, glass, sodium lauryl sulfate, talc, and titanium dioxide.  
**Questions or comments?** call 1-855-274-4122

Contains No Aspirin

LM-5284 P1432758

DISTRIBUTED BY:  
MIDWOOD BRANDS, LLC  
500 VOLVO PKWY.  
CHESAPEAKE, VA 23320 USA  
Made in India  
Code: TS/DRUGS/162014

**NVZ**

Lot:  
EXP:

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (100 Gelscaps Container Carton)**

**FAMILY  
Wellness™**

**COMPARE TO THE ACTIVE  
INGREDIENT IN EXTRA STRENGTH  
TYLENOL RAPID RELEASE GELS\***

**EXTRA STRENGTH  
PAIN RELIEF**

**RAPID  
RELEASE**

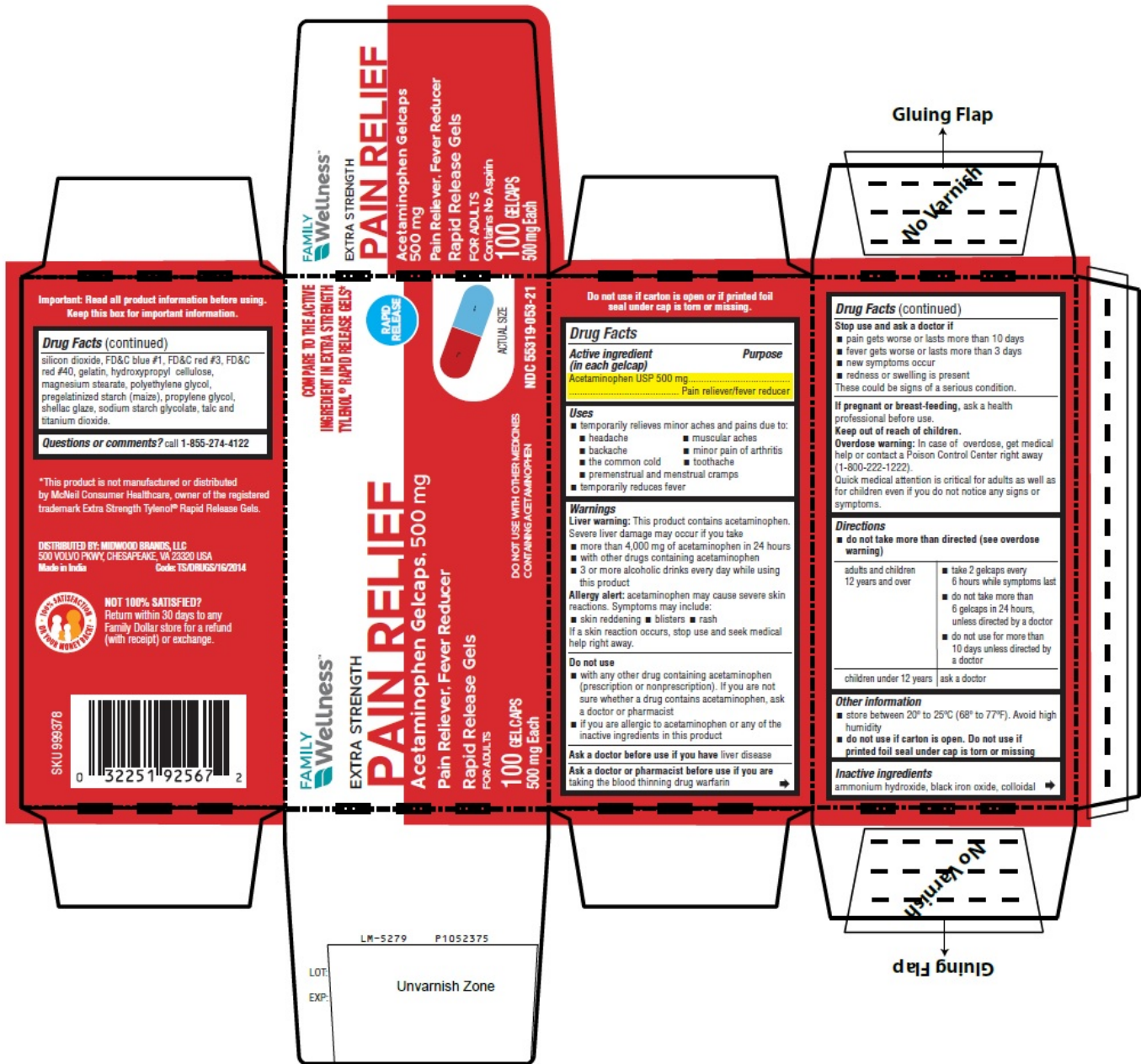
**Acetaminophen Gelscaps, 500 mg  
Pain Reliever, Fever Reducer  
Rapid Release Gels**

**FOR ADULTS**

**ACTUAL SIZE**

**100 GELCAPS  
500 mg Each  
ACETAMINOPHEN**

**DO NOT USE WITH OTHER MEDICINES  
CONTAINING  
NDC 55319-053-21**



## ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-053
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	red (and Blue with Grey Band)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	J;1
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-053-14	1 in 1 CARTON	08/11/2023	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55319-053-21	1 in 1 CARTON	08/11/2023	
2		100 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 Drug	M013	08/11/2023	

**Labeler** - Family Dollar Stores, LLC (024472631)

**Registrant** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	analysis(55319-053) , manufacture(55319-053)

Revised: 12/2023

Family Dollar Stores, LLC