# ACETAMINOPHEN- acetaminophen tablet, film coated, extended release Family Dollar Services, Inc.

-----

## Acetaminophen

**Drug Facts** 

## Active ingredient (in each caplet)

Acetaminophen USP, 650 mg

## **Purpose**

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - premenstrual and menstrual cramps
  - the common cold
  - headache
  - toothache
- temporarily reduces fever

#### Warnings

## Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 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

**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	<ul> <li>take 2 caplets every 8 hours with water</li> <li>swallow whole; do not crush, chew, split or dissolve</li> <li>do not take more than 6 caplets in 24 hours</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
under 18 years of age	• ask a doctor

#### Other information

- store at 20 25° C (68 77° F). Avoid excessive heat 40° C (104° F).
- see end panel for batch number and expiration date
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

#### **Inactive ingredients**

crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

## Questions?

call 1-800-406-7984

#### DISTRIBUTED BY: MIDWOOD BRANDS, LLC

500 Volvo Parkway, Chesapeake, VA 23320 USA

## PRINCIPAL DISPLAY PANEL - 650 mg Caplet Bottle Carton

**FAMILY** 

 $wellness^{TM}$ 

**COMPARE TO** 

TYLENOL® ARTHRITIS PAIN\*

**EASY** 

TO OPEN

**BOTTLE** 

Use only as directed.

NDC 55319-333-01

**ARTHRITIS** 

Pain Relief

Acetaminophen Extended-release Tablets USP, 650 mg

Pain Reliever/Fever Reducer

• For the Temporary Relief of Minor Arthritis Pain

Lasts up to

8 Hours

DO NOT USE WITH OTHER

MEDICINES CONTAINING

**ACETAMINOPHEN** 

**ACTUAL SIZE** 

THIS PACKAGE FOR

HOUSEHOLDS WITHOUT

YOUNG CHILDREN

100% SATISFACTION

OR YOUR MONEY BACK

**GUARANTEED** 

100 CAPLETS\* (\*Capsule-Shaped Tablets)



#### **ACETAMINOPHEN**

acetaminophen tablet, film coated, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-333	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	650 mg	

Inactive Ingredients			
Ingredient Name	Strength		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
PO VIDO NE, UNS PECIFIED (UNII: FZ989 GH94E)			
STARCH, CORN (UNII: O8232NY3SJ)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
CROSPO VIDO NE, UNSPECIFIED (UNII: 2S7830E561)			

Product Characteristics			
Color	white	Score	no score
Shape	OVAL (Capsule Shaped)	Size	19 mm
Flavor		Imprint Code	cor116
Contains			

1	Packaging			
#	t Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55319-333-23	24 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2017	
2	NDC:55319-333-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	09/01/2017	

## **Labeler** - Family Dollar Services, Inc. (024472631)

## Registrant - Ohm Laboratories Inc. (051565745)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	MANUFACTURE(55319-333)

Revised: 7/2020 Family Dollar Services, Inc.