

**PREMIER VALUE ARTHRITIS 8 HOUR- acetaminophen tablet, film coated, extended release
Premier Value**

PREMIER VALUE® ARTHRITIS 8 HOUR

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:
 - muscular aches
 - backache
 - minor pain of arthritis
 - toothache
 - premenstrual and menstrual cramps
 - headache
 - the common cold
- 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 and children 12 years and over	<ul style="list-style-type: none"> ▪ take 2 caplets every 8 hours with water ▪ swallow whole; do not crush, chew, split or dissolve ▪ do not take more than 6 caplets in 24 hours ▪ do not use for more than 10 days unless directed by a doctor
children under 12 years	<ul style="list-style-type: none"> ▪ do not use

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

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

Questions?

call **1-800-406-7984**

Distributed By:
Pharmacy Value Alliance, LLC
407 East Lancaster Avenue,
Wayne, PA 19087

PRINCIPAL DISPLAY PANEL - 650 mg Caplet Bottle Carton

COMPARE TO THE ACTIVE
INGREDIENT OF TYLENOL® 8 HOUR†

Premier Value®

Use only as directed.

Last up to 8 Hours

8 HOUR

Acetaminophen

Extended-release Tablets, USP, 650 mg

Pain Reliever/Fever Reducer

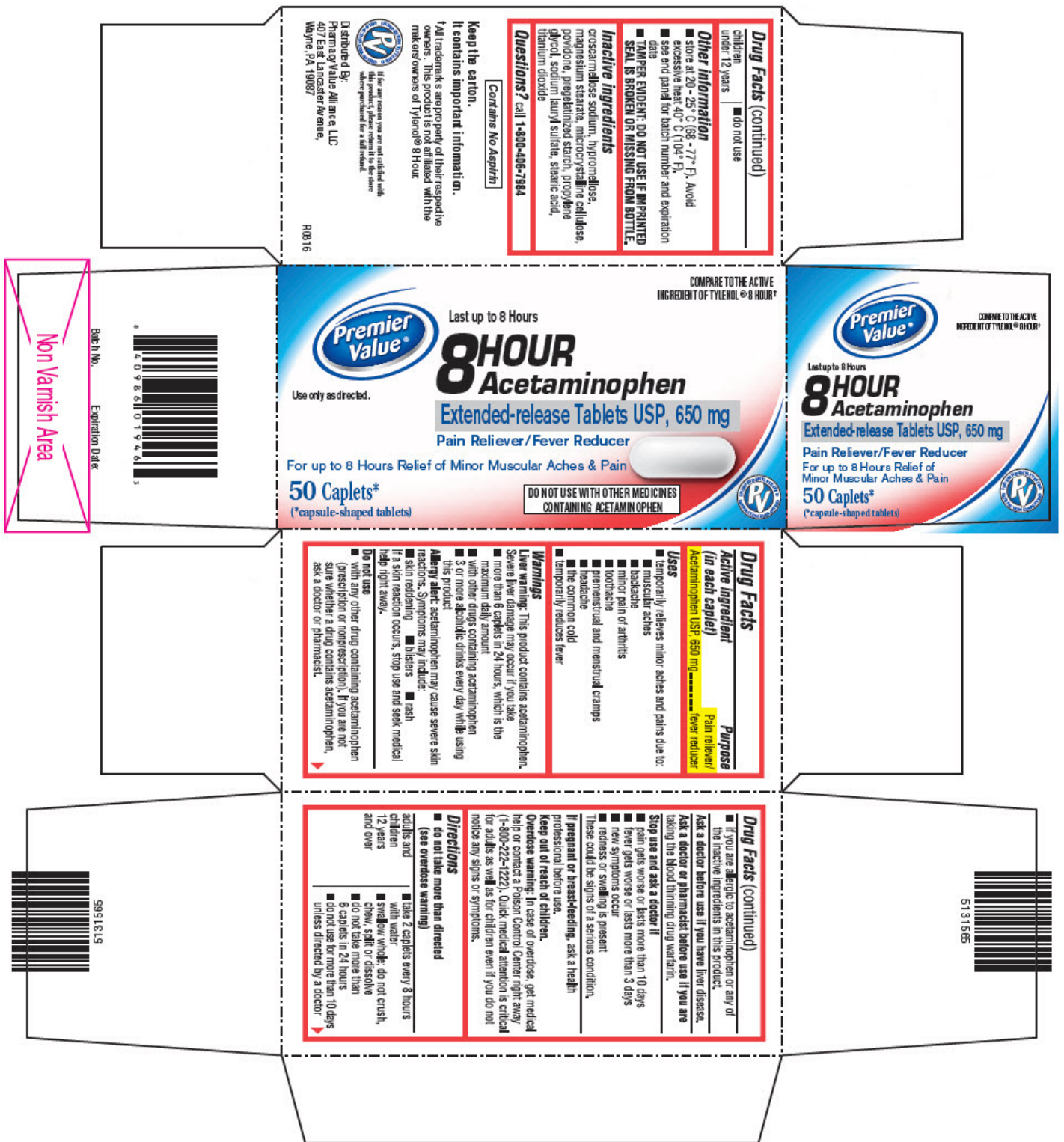
For up to 8 Hours Relief of Minor Muscular Aches & Pain

50 Caplets*

(*capsule-shaped tablets)

DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN

INDEPENDENTLY TESTED
SATISFACTION GUARANTEED



PREMIER VALUE ARTHRITIS 8 HOUR			
acetaminophen tablet, film coated, extended release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:680 16-336
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	650 mg	
Inactive Ingredients				
Ingredient Name		Strength		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white	Score	no score	
Shape	OVAL (Capsule Shaped)	Size	19mm	
Flavor		Imprint Code	cor116	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-336-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2002	
2	NDC:68016-336-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2002	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA076200	04/30/2002		

Labeler - Premier Value (101668460)

Registrant - Ohm Laboratories Inc. (051565745)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(68016-336)