# ACETAMINOPHEN- acetaminophen tablet, film coated, extended release Walgreen Company

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# 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	<ul><li>ask a doctor</li></ul>

## 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, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

# Questions?

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

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

# PRINCIPAL DISPLAY PANEL - 650 mg Caplet Bottle Carton

Walgreens

Compare to Tylenol<sup>®</sup> 8 HR Arthritis Pain active ingredient<sup>††</sup> NDC 0363-0334-22

Arthritis

Pain Reliever

ACETAMINOPHEN EXTENDED-RELEASE TABLETS USP, 650 mg / PAIN RELIEVER / FEVER REDUCER

**ARTHRITIS** 

8 HOUR

**CAPLETS** 

- For the temporary relief of minor arthritis pain
- Lasts up to 8 hours

**ACTUAL SIZE** 

225

CAPLETS\*

(\*CAPSULE-SHAPED TABLETS)

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

**USE ONLY AS DIRECTED** 

Arthritis Pain active ingredient Compare to Tylenol® 8 HR

# Walgreens

Compare to Tylenol® 8 HR Arthritis Pain active ingredient

NDC 0363-0334-22

ACETAMINOPHEN EXTENDED-RELEASE TABLETS USP, 650 mg/ PAIN RELIEVER / FEVER REDUCER

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5 (\*CAPSULE-SHAPED TABLETS)

**ACETAMINOPHEN** EXTENDED-RELEASE

TABLETS USP, 650 mg / PAIN RELIEVER

EVER REDUCER

ARTHRITIS

HOUR

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Active ingredient Drug Facts

## DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN USE ONLY AS DIRECTED

Warnings

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toothache

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premenstrual and menstrual cramps

backache muscular aches minor pain of arthritis

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# Stop use and ask a doctor if

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# Do not use

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- if you are allergic to acetaminophen or any of the or pharmacist. inactive ingredients in this product.

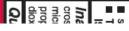
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the blood thinning drug warfarin

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200 WILMOT RD., DEEPRELD, IL 60015

WALGRAGEMAL

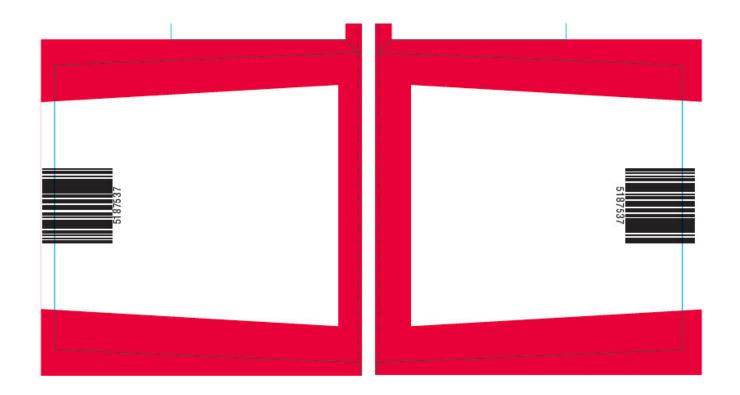
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Non Varnish Area







# **ACETAMINOPHEN**

acetaminophen tablet, film coated, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0334	
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	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
STARCH, CORN (UNII: O8232NY3SJ)		
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

# **Product Characteristics**

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

	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NDC:0363-0334-55	150 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2002	
	2 NDC:0363-0334-22	225 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 - Walgreen Company (008965063)

# Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ohm Laboratories Inc.		184769029	MANUFACTURE(0363-0334)	

Revised: 8/2018 Walgreen Company