

**ACETAMINOPHEN- acetaminophen tablet, film coated, extended release**  
**American Sales Company**

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**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
  - headache
  - toothache
  - the common cold
  - premenstrual and menstrual cramps
- 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

**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)**

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adults	<ul style="list-style-type: none"><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 style="list-style-type: none"><li>▪ ask a doctor</li></ul>

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## **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**

## **PRINCIPAL DISPLAY PANEL**

**Compare to the Active Ingredient in Tylenol® Arthritis Pain†  
CAREONE®**

**Use only as directed.**

**See New Warnings Information**

**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**

**100 CAPLETS\* 650 mg Each**

\* Capsule-Shaped Tablets

DISTRIBUTED BY: AMERICAN SALES COMPANY

5095106/R0412

Non Varnish Area

Batch No. 3  
41520 31694  
Expiration Date 4

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

Compare to the Active Ingredient in Tylenol® Arthritis Pain!

## CARONE®

Use only as directed. See New Warnings Information

# 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

100 CAPLETS\*  
650 mg Each  
\*Capsule-Shaped Tablets

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## CARONE®

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Acetaminophen Extended-Release Tablets, USP 650 mg  
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LASTS UP TO 8 HOURS

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

100 CAPLETS\*  
650 mg Each  
\*Capsule-Shaped Tablets

**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:

- toothache
- headache
- the common cold
- premenstrual and menstrual cramps
- temporary reduces fever

**Warnings:** Liver damage may occur if you take more than 10 capsules in 24 hours, which is the maximum dose. Do not use with other drugs containing acetaminophen. 3 or more alcoholic drinks every day while using this product. Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure if your 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:

- you get a rash that lasts more than 10 days
- you get a fever that lasts more than 3 days
- new symptoms occur
- redness or swelling in present
- you are pregnant or breast-feeding, ask a health professional for advice before use during pregnancy or while breastfeeding. Keep out of reach of children. Overdose warnings: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical!

**Drug Facts (continued)**

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)
- take 2 caplets every 8 hours with adults
  - water
  - with 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
- ask a doctor

19 years of age

**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

**Inactive Ingredients:** croscarmellose sodium, hydroxyethylcellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polydioxane, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

**Questions?** call 1-800-406-7994

Contains No Aspirin

This product is not manufactured or distributed by McNeil Consumer Healthcare, Inc. The owner of the registered trademark "Tylenol" is the Tylenol Company.

**Keep this carton. It contains important information.**

DISTRIBUTED BY:  
AMERICAN SALES COMPANY  
4201 WARDEN AVENUE  
LANCASTER, NY 14086  
www.carone1.info  
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Quality guaranteed or your money back.

R0412

9015605

5095106

acetaminophen tablet, film coated, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-333
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-333-01	100 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	04/30/2002	

**Labeler** - American Sales Company (809183973)

**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)

## Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(41520-333)

Revised: 1/2013

American Sales Company