

**ACETAMINOPHEN- acetaminophen tablet, film coated, extended release**  
**Shopko Stores Operating Co., LLC**

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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	ask a doctor

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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**

**SHOPKO®**

**Compare to the active ingredient of Tylenol® Arthritis Pain†**

**Use only as directed.**

**See New Warnings Information**

**Arthritis Pain Relief**

**Acetaminophen Extended-Release Tablets, USP 650 mg**

**Pain Reliever/Fever Reducer**

**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

**EASY OPEN**

**Lasts up to 8 hours**

**For the temporary relief of minor arthritis pain**

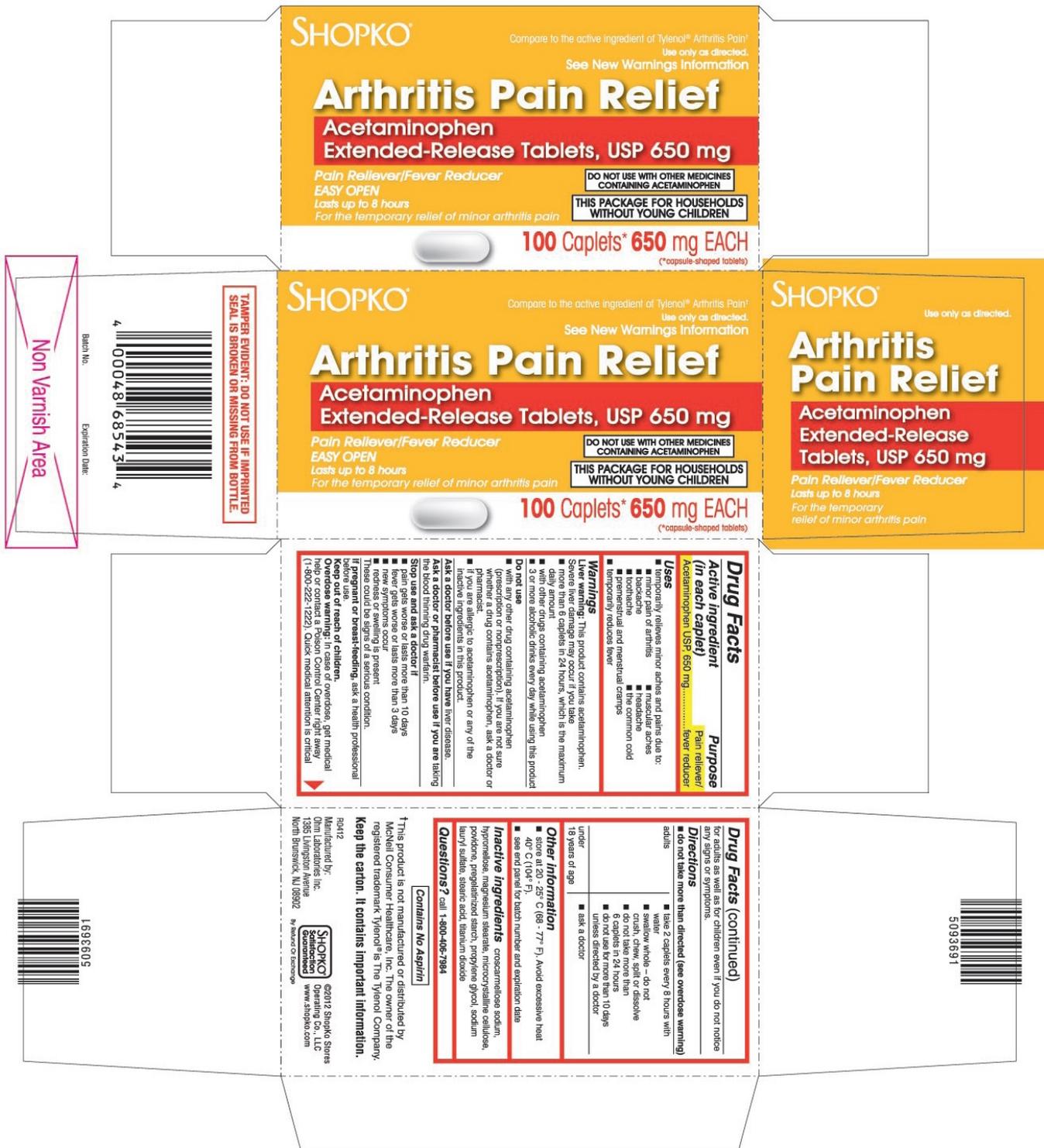
**THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN**

**100 Caplets \*650 mg EACH**

**(\*capsule-shaped tablets)**

**Manufactured by: Ohm Laboratories Inc.**

**5093691/R0412**



# ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37012-333
<b>Route of Administration</b>	ORAL		

<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	650 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
CROSCARMELOSE 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)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
<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>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:370 12-333-01	100 in 1 BOTTLE		
2	NDC:370 12-333-04	250 in 1 BOTTLE		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA076200	04/30/2002		

**Labeler** - Shopko Stores Operating Co., LLC (023252638)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(370 12-333)