

**ACETAMINOPHEN- acetaminophen tablet, film coated, extended release**  
**Amerisource Bergen**

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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:
  - muscular aches
  - backache
  - headache
  - minor pain of arthritis
- 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 and children 12 years and over

- 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

- do not use
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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**

**GOOD NEIGHBOR PHARMACY®**

**Compare to Tylenol® 8 Hour active ingredient†**

**NDC 46122-0062-71**

**Lasts up to 8 Hour**

**Use only as directed.**

**See New Warnings Information**

**acetaminophen extended-release tablets, USP 650 mg**

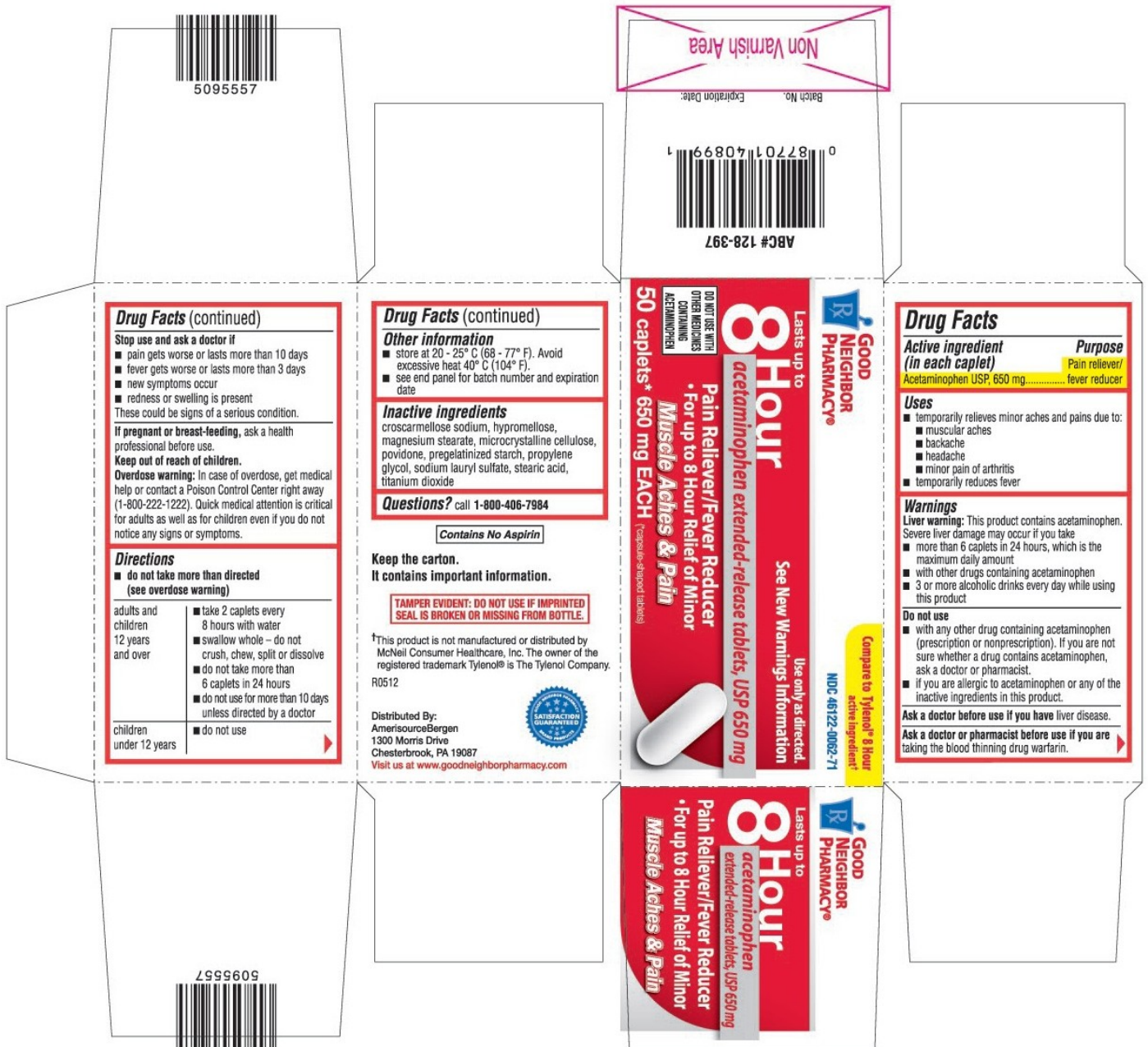
**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

**Pain Reliever/Fever Reducer**

- **For up to 8 Hour Relief of Minor Muscle Aches & Pain**

**50 caplets\* 650 mg EACH (\*capsule-shaped tablets)**

**Distributed By: AmerisourceBergen**



ACETAMINOPHEN			
acetaminophen tablet, film coated, extended release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-062
Route of Administration	ORAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg		
<b>Inactive Ingredients</b>				
Ingredient Name	Strength			
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)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
Color	white	Score	no score	
Shape	OVAL (Capsule Shaped)	Size	19mm	
Flavor		Imprint Code	cor116	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-062-71	50 in 1 BOTTLE		
2	NDC:46122-062-78	100 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** - Amerisource Bergen (007914906)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(46122-062)