LEADER ARTHRITIS PAIN RELIEVER- acetaminophen tablet, film coated, extended release
Cardinal Health

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)**

adults:

- 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

under 18 years of age:

- ask a doctor

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

QUESTIONS?

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

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE. (*for bottle cartons/label and stand-alone labels only)*

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN. *(for non CRC packages)*

Contains No Aspirin

Keep the carton. It contains important information.

DISTRIBUTED BY

CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

1-800-200-6313

PRINCIPAL DISPLAY PANEL

LEADER®

NDC 37205-034-78

EASY TO OPEN BOTTLE

See New Warnings Information

Use only as directed.

Lasts up to 8 hours

Arthritis Pain Reliever

Acetaminophen Extended-Release Tablets, USP 650 mg

Pain Reliever/Fever Reducer

For the Temporary Relief of Minor Arthritis Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

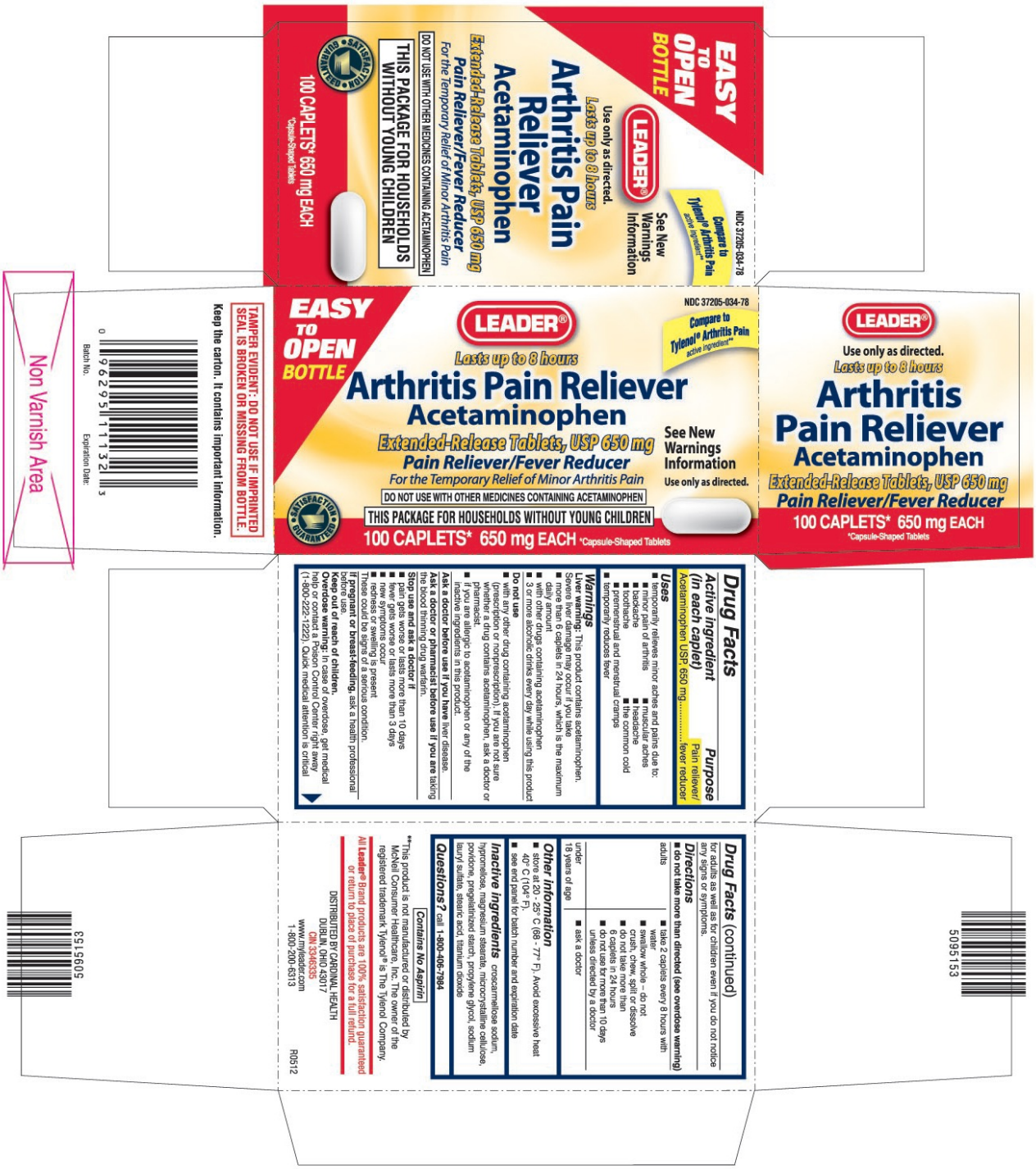
THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

100 CAPLETS* 650 mg EACH

***Capsule-Shaped Tablets**

Compare to Tylenol® Arthritis Pain active ingredient**

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



100's bottle carton

LEADER ARTHRITIS PAIN RELIEVER

acetaminophen tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-034
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**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

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:37205-034-71	50 in 1 BOTTLE		
2	NDC:37205-034-78	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 - Cardinal Health (097537435)

Registrant - Ohm Laboratories Inc. (051565745)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture

Revised: 3/2012 Cardinal Health