

LEADER 8 HOUR 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:
 - 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)**

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

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 37205-477-78

Use only as directed.

Lasts up to 8 Hour Pain Reliever

Acetaminophen Extended-Release Tablets, USP 650 mg

Pain Reliever/Fever Reducer

For up to 8 Hour Relief of Minor Muscular Aches & Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

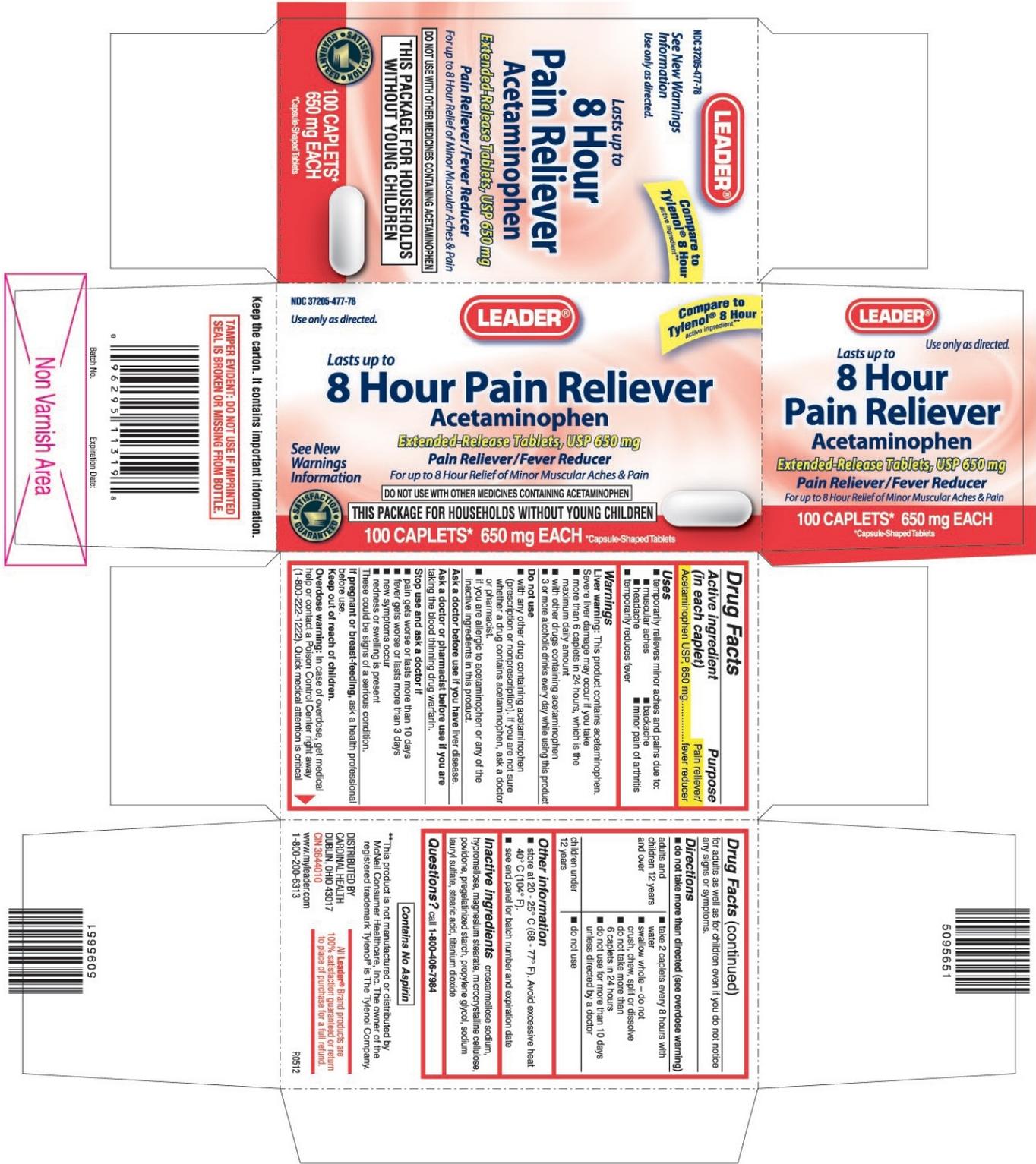
THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

100 CAPLETS* 650 mg EACH

***Capsule-Shaped Tablets**

Compare to Tylenol[®] 8 Hour 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 8 HOUR PAIN RELIEVER
acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-477
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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)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
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:37205-477-78	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

