ACETAMINOPHEN- acetaminophen tablet, extended release
Cardinal Health

Drug Facts

ACTIVE INGREDIENT (IN EACH GELTAB)

Acetaminophen USP, 650 mg

PURPOSE

Pain reliever/fever reducer

USES

- temporarily relieves minor aches and pains due to:
  - muscular aches
  - backache
  - headache
  - toothache
  - the common cold
  - minor pain of arthritis
  - premenstrual and menstrual cramps
- temporarily reduces fever

WARNINGS

Liver warning: This product contains acetaminophen. Sever liver damage may occur if you take

- more than 6 geltabs 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 have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets.
- 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

- the tablet got stuck in your throat

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 geltabs every 8 hours. Swallow only one geltab at a time. ▪ take a sip of water before swallowing each geltab and wash each geltab down with water (up to a full 8 oz. glass). ▪ swallow whole - do not crush, chew, split or dissolve ▪ do not take more than 6 geltabs 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 high humidity.
- 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, gelatin, glycerin, hypromellose, iron oxide black, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, starch, titanium dioxide

QUESTIONS?

Call **1-800-406-7984**

PRINCIPAL DISPLAY PANEL

NDC 37205-662-58

LEADER®

Compare to Tylenol Arthritis Pain active ingredient†

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

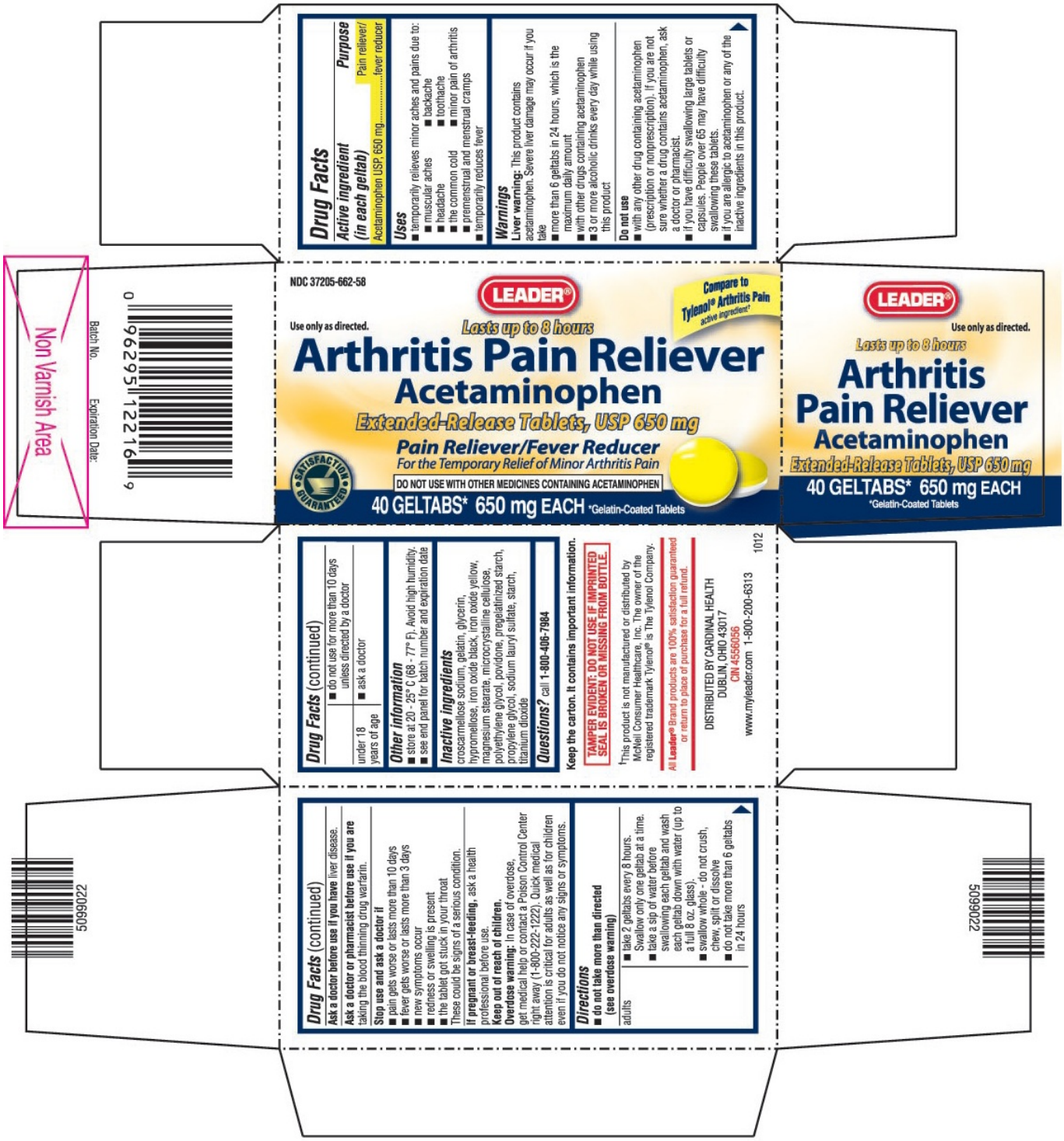
DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

40 GELTABS*650 mg EACH

***Gelatin-Coated Tablets**

DISTRIBUTED BY CARDINAL HEALTH

5099022/1012



ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-662
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (White to Yellow)	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	350
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-662-58	40 in 1 BOTTLE		
2	NDC:37205-662-57	80 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078569	12/21/2012	

Labeler - Cardinal Health (097537435)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(37205-662)