ACETAMINOPHEN - acetaminophen tablet, extended release
Aurohealth LLC

Drug Facts

Active ingredient (in each extended-release tablet)

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
  - premenstrual and menstrual cramps
  - the common cold
  - headache
  - toothache
- temporarily reduces fever

Warnings

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

- more than 6 tablets 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

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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 tablets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 tablets 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 20º to 25ºC (68º to 77ºF). Avoid excessive heat 40ºC (104ºF).
- **do not use if carton is opened or foil inner seal is broken**
- Meets USP dissolution test 3

Inactive ingredients

colloidal silicon dioxide, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch (maize), sodium starch glycolate, titanium dioxide, triacetin

Questions or comments?
call **1-855-274-4122**

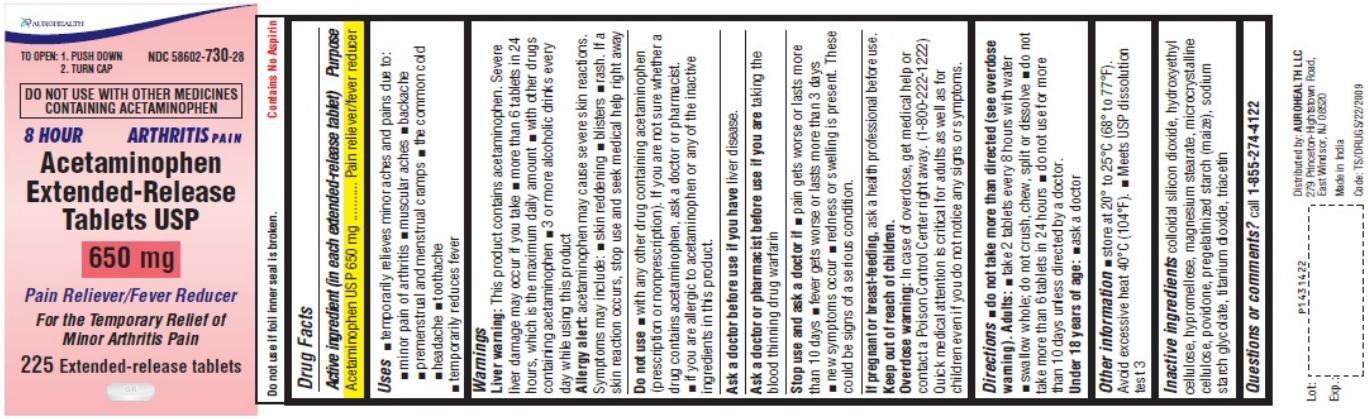
Distributed by:
AUROHEALTH LLC
279 Princeton-Hightstown Road,
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

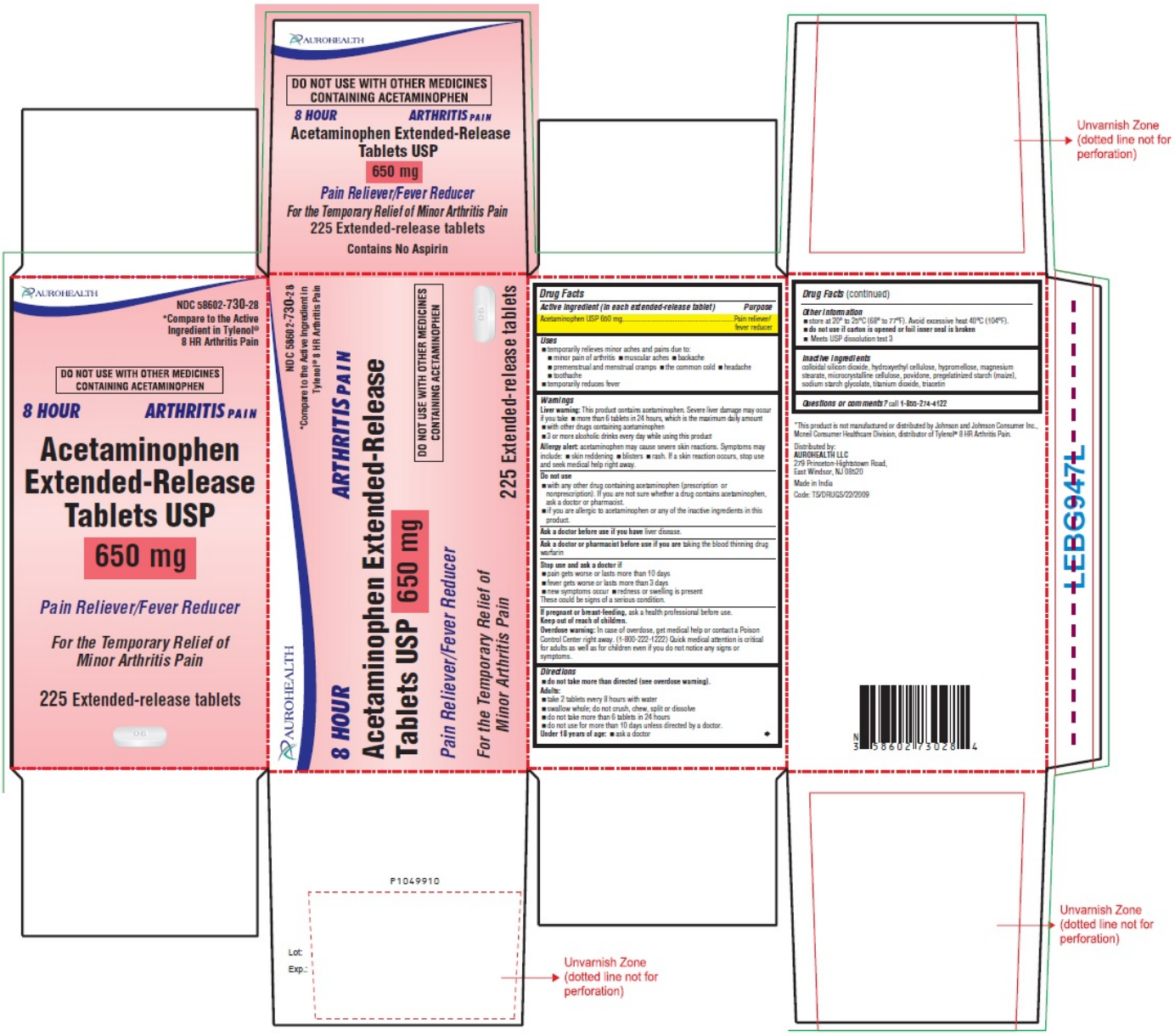
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (225 Tablets Bottle)

AUROHEALTH
TO OPEN: 1. PUSH DOWN NDC 58602-730-28
2. TURN CAP
DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN
8 HOUR ARTHRITIS PAIN
Acetaminophen
Extended-Release
Tablets USP
650 mg
Pain Reliever/Fever Reducer
For the Temporary Relief of
Minor Arthritis Pain
225 Extended-release tablets



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (225 Tablets Container Carton)

AUROHEALTH
NDC 58602-730-28
***Compare to the Active Ingredient in Tylenol®**
8 HR Arthritis Pain
DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN
8 HOUR ARTHRITIS PAIN
Acetaminophen Extended-Release Tablets USP
650 mg
Pain Reliever/Fever Reducer
For the Temporary Relief of Minor Arthritis Pain
225 Extended-release tablets



ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-730
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	WHITE (White to Off-White)	**Score**	no score
Shape	CAPSULE (Caplet)	**Size**	19mm
Flavor		**Imprint Code**	I;06
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-730-36	1 in 1 CARTON	11/09/2016	
1		250 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-730-07	1 in 1 CARTON	08/11/2018	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		

3	NDC:58602-730-14	1 in 1 CARTON	08/11/2018	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-730-21	1 in 1 CARTON	08/11/2018	
4		100 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-730-29	150 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2018	
6	NDC:58602-730-34	200 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2018	
7	NDC:58602-730-35	225 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2018	
8	NDC:58602-730-67	290 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2018	
9	NDC:58602-730-76	325 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2018	
10	NDC:58602-730-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2018	
11	NDC:58602-730-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2018	
12	NDC:58602-730-94	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2020	
13	NDC:58602-730-44	400 in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2021	
14	NDC:58602-730-28	1 in 1 CARTON	12/29/2021	
14		225 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207229	11/09/2016	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-730) , MANUFACTURE(58602-730)

Revised: 1/2024 Aurohealth LLC