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**
- USP Dissolution test is pending

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
2572 Brunswick Pike
Lawrenceville, NJ 08648

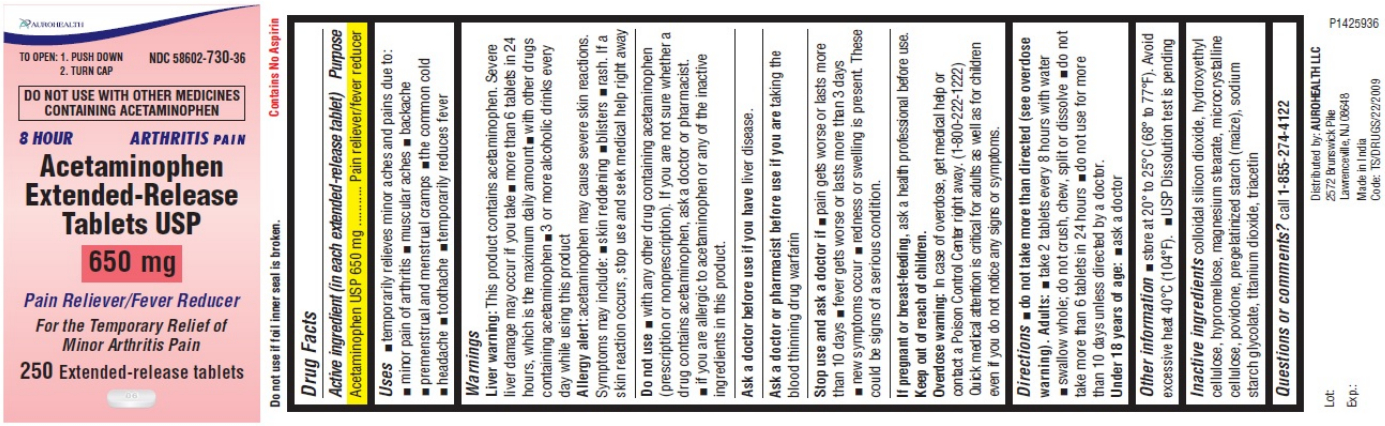
Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (250 Tablet Bottle)

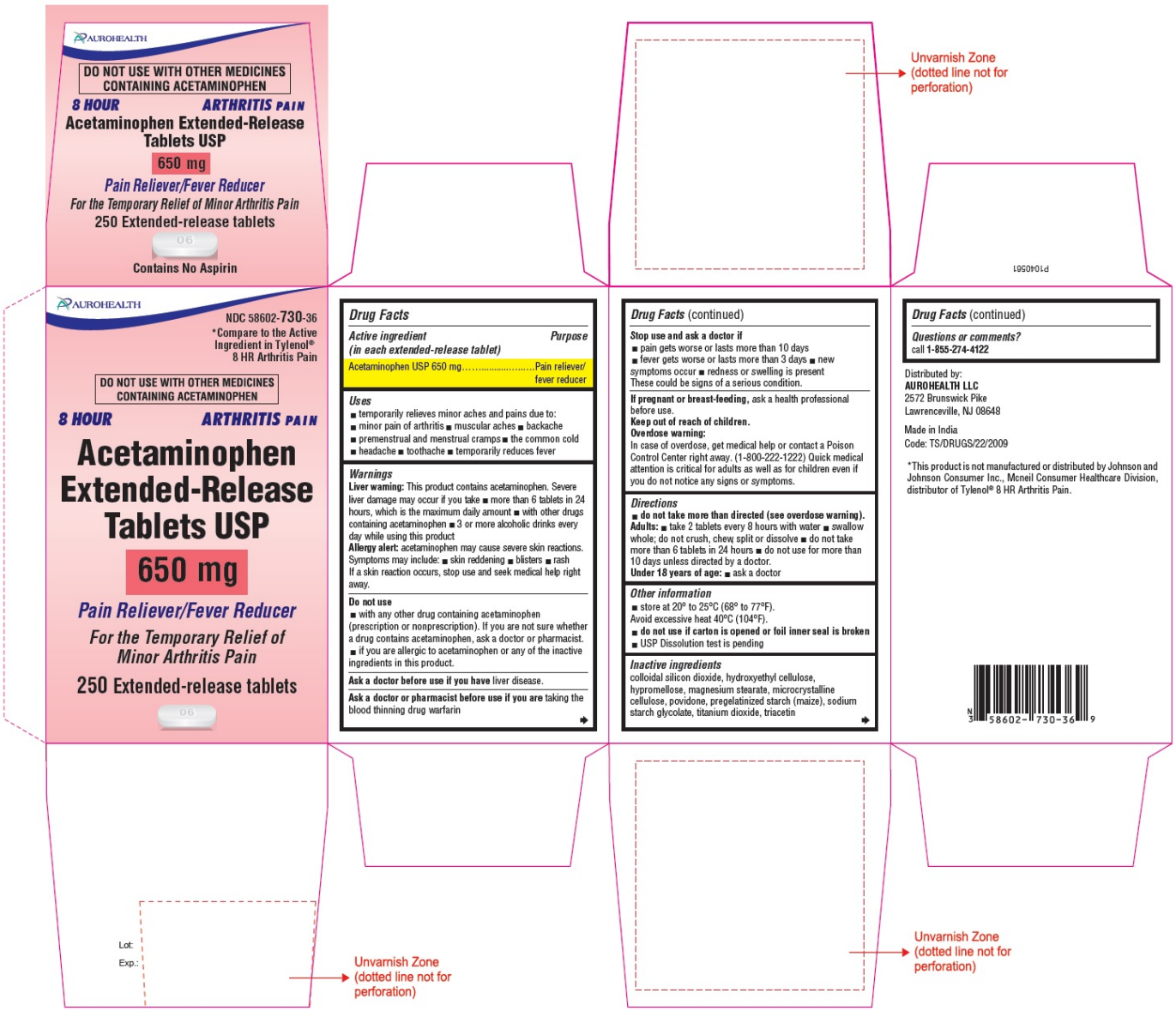
AUROHEALTH

TO OPEN: 1. PUSH DOWN NDC 58602-730-36
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
250 Extended-release tablets



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (250 Tablets Container Carton)

AUROHEALTH
NDC 58602-730-36
***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
250 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	

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: 4/2020

Aurohealth LLC