ACETAMINOPHEN - acetaminophen tablet, extended release
WALGREEN CO.

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: WALGREENS CO.
200 WILMOTRD., DEERFIELD, IL 60015

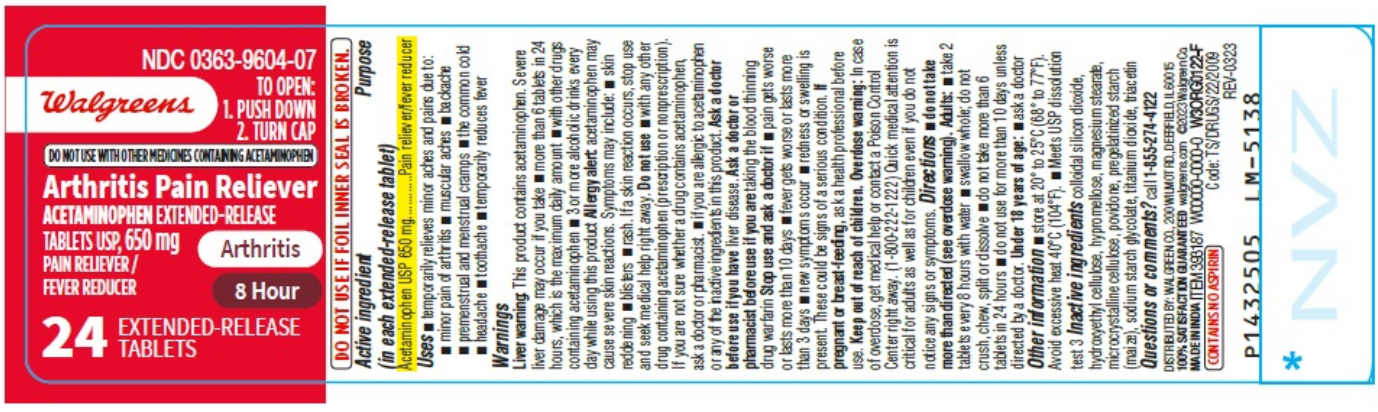
MADE IN INDIA

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (24 Tablet Container Label)

NDC 0363-9604-07
Walgreens

TO OPEN:
1. PUSH DOWN
2. TURN CAP
DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN
Arthritis Pain Reliever
ACETAMINOPHEN EXTENDED-RELEASE
TABLETS USP, 650 mg
PAIN RELIEVER /
FEVER REDUCER
Arthritis
8 Hour
24 EXTENDED-RELEASE
TABLETS



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (24 Tablets Container Carton)

NDC 0363-9604-07

Walgreens

Compare to the active ingredient in Tylenol® 8HR Arthritis Pain††

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

Arthritis Pain Reliever

ACETAMINOPHEN EXTENDED-RELEASE TABLETS USP, 650 mg

PAIN RELIEVER / FEVER REDUCER

Arthritis 8 Hour

. For the temporary relief of minor arthritis pain

24 EXTENDE-RELEASE TABLETS **Actual Size**

ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-9604
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:0363-9604-07	1 in 1 CARTON	07/07/2021	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-9604-35	1 in 1 CARTON	07/07/2021	
2		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	07/07/2021	

Labeler - WALGREEN CO. (008965063)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(0363-9604) , MANUFACTURE(0363-9604)

Revised: 5/2024 WALGREEN CO.