ACETAMINOPHEN- acetaminophen tablet
BluePoint Laboratories

Acetaminophen Extended-Release Tablets, USP 650mg

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 ue 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

Manufactured by:
Aurobindo Pharma Limited
Unit-VII (SEZ), Mahabubnagar (Dt)-509302, India.

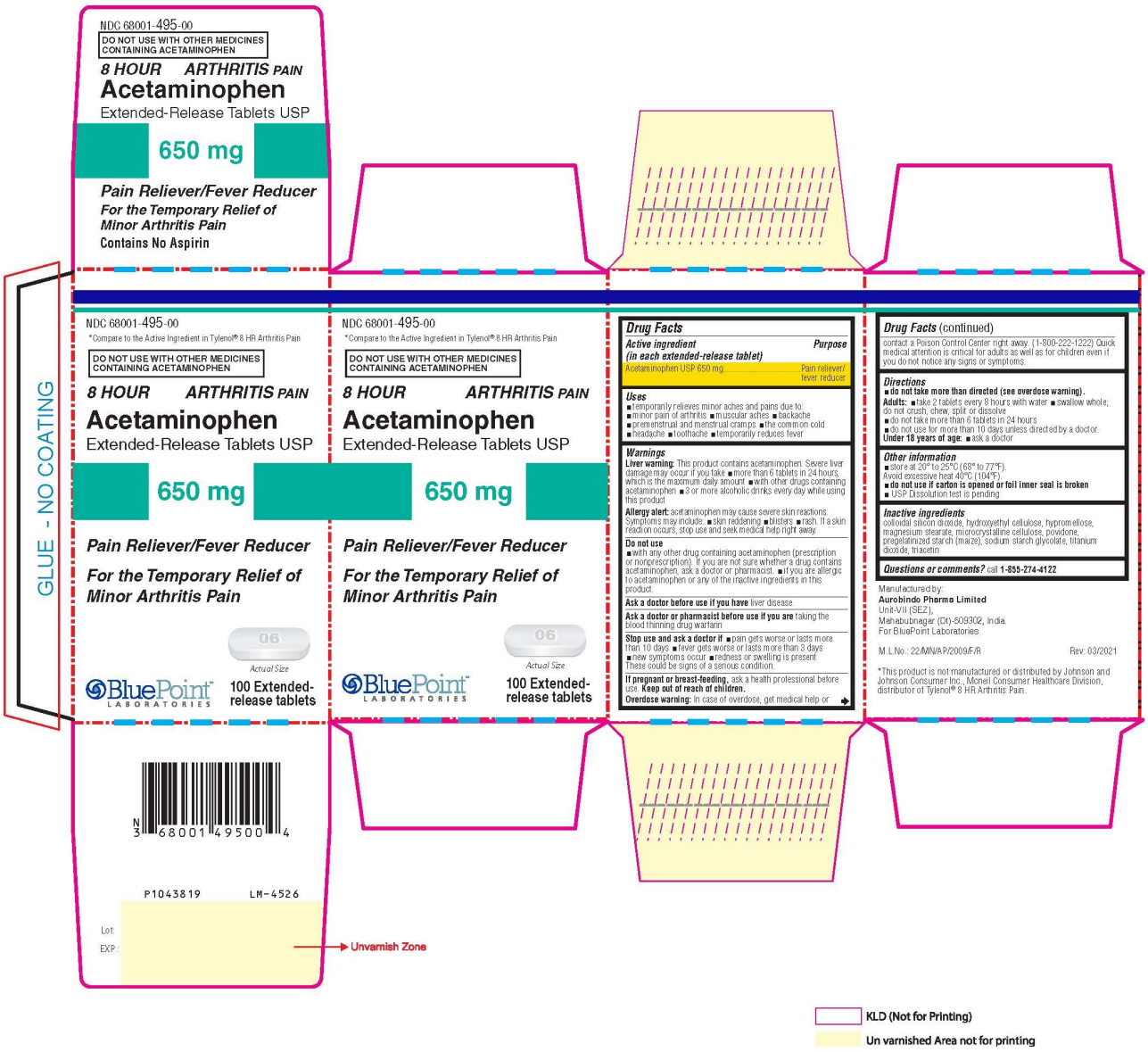
For BluePoint Laboratories

Rev: 03/2021

M.L. No.: 22/MN/AP/2009/F/R

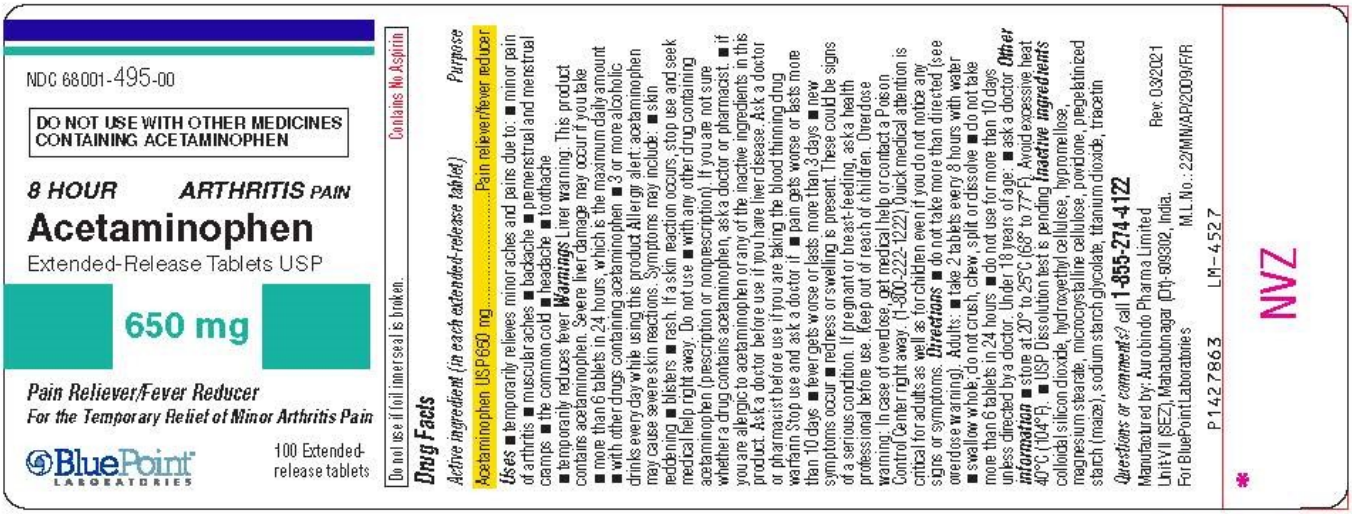
Package Label - Principal Display Panel

Acetaminophen Extended-Release tablets USP 650mg (100 tablets Carton) NDC: 68001-495-00



Acetaminophen Extended-Release tablets USP 650mg (100 tablets Container Label)
NDC: 68001-495-00

Unwinding Direction



A/s: 120 x 45 mm

Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of L
printed online during

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68001-495
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
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

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:68001-495-00	1 in 1 CARTON	04/30/2021	
1		100 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	04/30/2021	

Labeler - BluePoint Laboratories (985523874)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Ltd		650381903	analysis(68001-495) , manufacture(68001-495)

Revised: 4/2021 BluePoint Laboratories