ARTHRITIS PAIN RELIEVER- acetaminophen tablet, film coated, extended release
American Health Packaging

Acetaminophen Extended-Release Tablets, USP
Pain Reliever/Fever Reducer
8277725/0121

Drug Facts

Active ingredient (in each caplet)
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 caplets 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 caplets every 8 hours with water • swallow whole; do not crush, chew, split or dissolve • do not take more than 6 caplets 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° to 25°C (68° to 77°F). Avoid excessive heat 40°C (104°F).
- **FOR YOUR PROTECTION:** Do not use if blister is torn or broken.
- supplied as unit dose packages of 30 (5 x 6) NDC 68084-777-25

Inactive ingredients

crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium

dioxide

Questions?

- about the drug product, call Sun Pharmaceutical Industries, Inc. at 1-800-406-7984
- about the packaging, call American Health Packaging at 1-800-707-4621

Contains No Aspirin

PACKAGING INFORMATION
American Health Packaging unit dose blisters contain drug product from Ohm Laboratories Inc. as follows:
(650 mg / 30 UD) NDC 68084-777-25 packaged from NDC 51660-333

Distributed by:
American Health Packaging
Columbus, OH 43217

8277725/0121

Principal Display Panel – Carton – 650 mg

NDC 68084-**777**-25

Acetaminophen

Extended-release Tablets, USP

Pain Reliever/Fever Reducer

650 mg

30 Tablets (5 x 6)

(01) 0 03 68084 777 25 7

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

NDC 68084-**777**-25

Acetaminophen

Extended-release Tablets, USP

Pain Reliever/Fever Reducer

650 mg

30 Tablets (5 x 6)

Drug Facts

Active ingredient (in each caplet)	***Purpose***
Acetaminophen USP, 650 mg	Pain reliever/fever reducer

Uses

See package insert for complete Drug Facts information.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 6 caplets 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.

Keep out of reach of children.

See package insert for additional Drug Facts warnings.

Directions

■ do not take more than directed, see package insert for overdose warning and complete Drug Facts information.

Other Information ■ store at 20° to 25°C (68° to 77°F). Avoid excessive heat 40°C (104°F). ■ **FOR YOUR PROTECTION: Do not use product if blister is torn or broken.**

Contains No Aspirin

The drug product contained in this package is from NDC # 51660-333, Ohm Laboratories Inc.

Distributed by: American Health Packaging
2550 John Glenn Avenue, Suite A
Columbus, OH 43217

077725
0277725/0222

NDC 68084- **777**-25

Acetaminophen
Extended-release Tablets, USP
Pain Reliever/Fever Reducer

650 mg

30 Tablets (5 x 6)

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN.

Drug Facts

Active Ingredient (in each caplet) ***Purpose***

Acetaminophen USP, 650 mg ..... Pain reliever/fever reducer

Uses

See package insert for complete Drug Facts information.

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Avoid excessive heat 40°C (104°F). • **FOR YOUR PROTECTION: Do not use product if blister is torn or broken.**

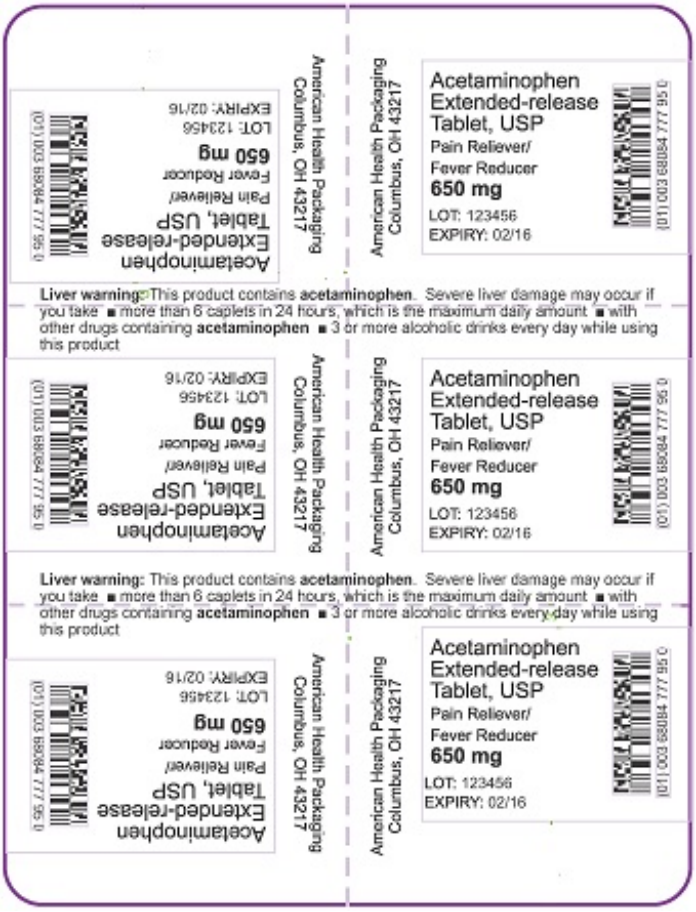
Contains No Aspirin

The drug product contained in this package is from NDC # 51660-333, Ohm Laboratories Inc.

Distributed by: American Health Packaging
2550 John Glenn Avenue, Suite A
Columbus, OH 43217

077725
0277725/0222

Principal Display Panel – Blister – 650 mg



Acetaminophen
Extended-release
Tablet, USP
Pain Reliever/
Fever Reducer

650 mg

ARTHRITIS PAIN RELIEVER

acetaminophen tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68084-777(NDC:51660-333)
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**
CROSPOVIDONE (UNII: 2S7830E561)	

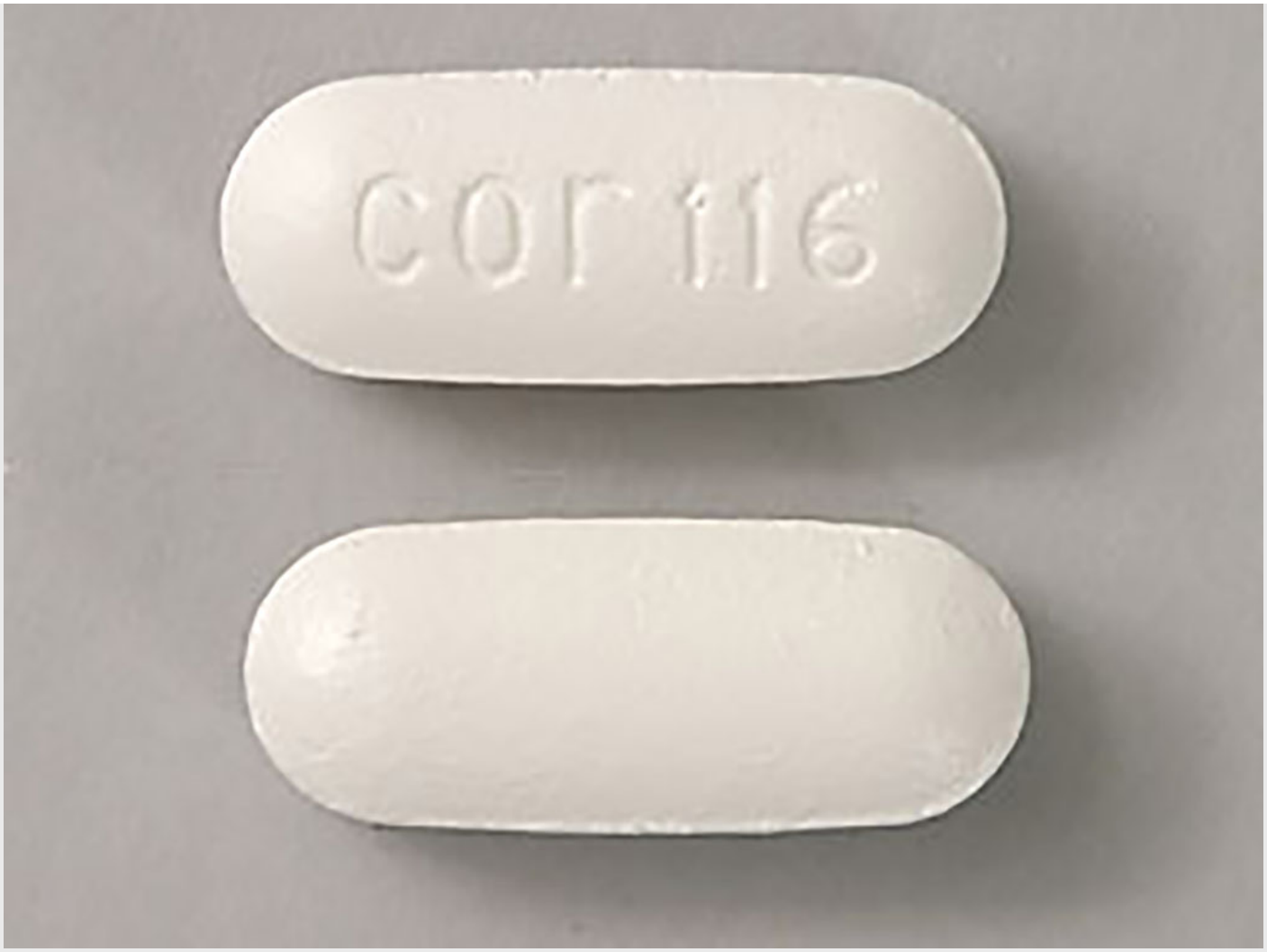
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL (Capsule Shaped)	**Size**	19mm
Flavor		**Imprint Code**	cor116
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68084-777-25	30 in 1 BOX, UNIT-DOSE	08/18/2014	
1	NDC:68084-777-95	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	08/18/2014	

Labeler - American Health Packaging (929561009)

Establishment

Name	Address	ID/FEI	Business Operations
American Health Packaging		929561009	repack(68084-777)

Revised: 6/2022 American Health Packaging