

ACETAMINOPHEN- acetaminophen tablet, film coated, extended release
CVS Pharmacy

Acetaminophen

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	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ ask a doctor

Other information

- store at 20 - 25° C (68 - 77° F). Avoid excessive heat 40° C (104° F).
- see end panel for batch number and expiration date
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**

Inactive ingredients

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

Questions?

call **1-800-406-7984**

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 650 mg Caplet Bottle Carton

CVSHealth™

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

Caplets[†]

8HR Arthritis

Pain Relief

ACETAMINOPHEN

EXTENDED-RELEASE TABLETS, USP 650 mg

Pain reliever; Fever reducer

- For the temporary relief of minor arthritis pain
- Lasts up to 8 hours

DO NOT USE WITH OTHER
MEDICINES CONTAINING
ACETAMINOPHEN

Use only as directed.

24 CAPLETS[†]

[†]CAPSULE-SHAPED TABLETS

Actual Size

Drug Facts (continued)

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Contains No Aspirin

Keep the carton.

It contains important information.

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
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CVS.com® 1-800-SHOP CVS

V-10981

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Money Back Guarantee

PLEASE RECYCLE



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

Caplets†

8HR Arthritis Pain Relief

ACETAMINOPHEN
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Drug Facts (continued)

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Caplets[†]

CVS
Health™

**8HR Arthritis
Pain Relief**
ACETAMINOPHEN

*All trademarks are the property of their respective owners. This product is a registered trademark of the makers/owners of Tylenol.

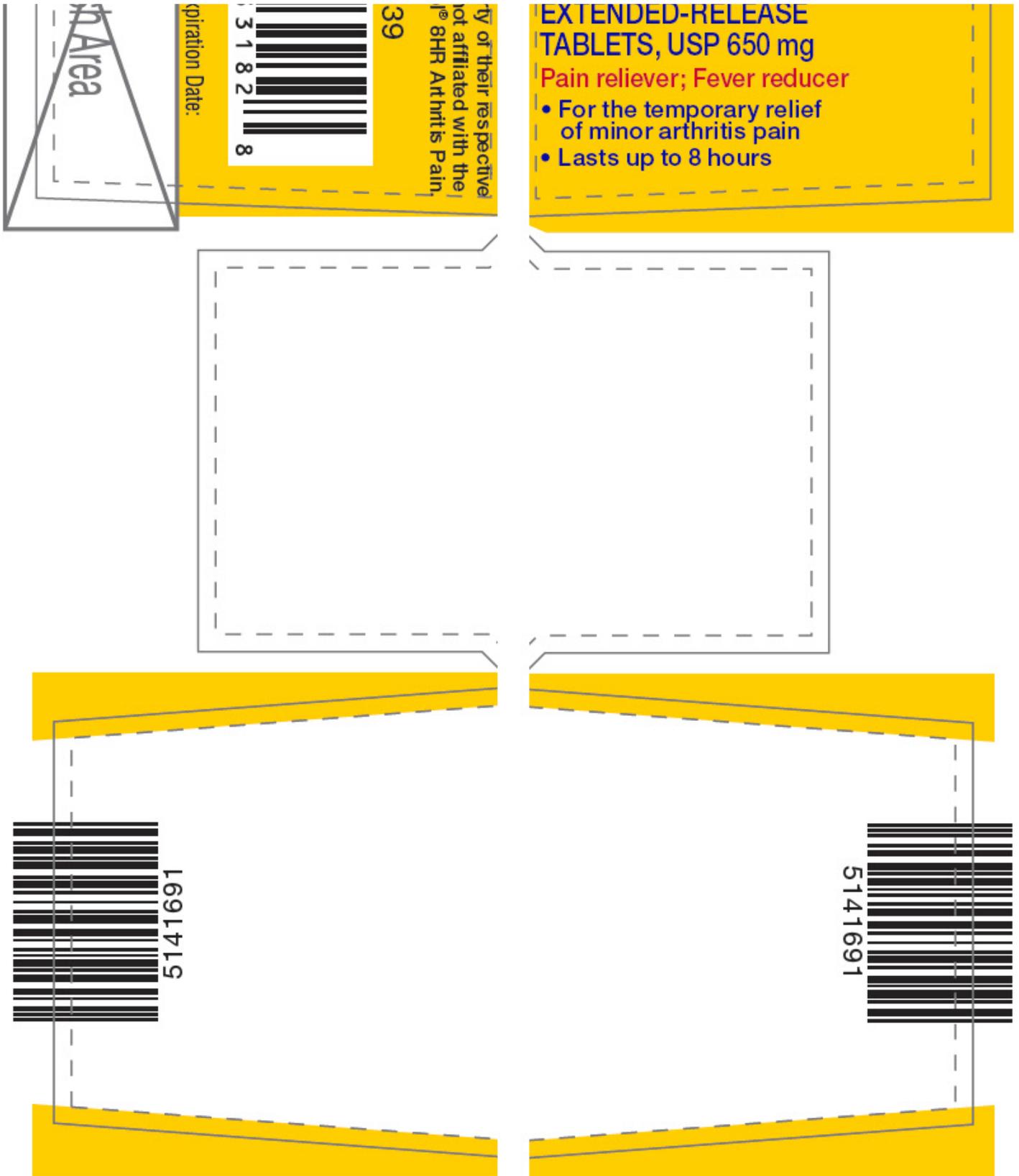
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Batch No.

Ex

~~Non-Variants~~



ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59779-350

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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
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:59779-350-23	24 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2002	
2	NDC:59779-350-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2002	
3	NDC:59779-350-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2002	
4	NDC:59779-350-55	150 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2002	
5	NDC:59779-350-04	250 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2002	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	04/30/2002	

Labeler - CVS Pharmacy (062312574)

Registrant - Sun Pharmaceutical Industries Inc. (146974886)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(59779-350)

Revised: 12/2019

CVS Pharmacy