

ACETAMINOPHEN- acetaminophen tablet, film coated, extended release
Safeway Inc.

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
 - headache
 - toothache
 - the common cold
 - premenstrual and menstrual cramps

- 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

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 have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets.
- 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

- the tablet got stuck in your throat
- 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: Taking more than the recommended dose (overdose) may cause liver damage. 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 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
children under 18 years of age	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

PRINCIPAL DISPLAY PANEL

Lasts up to 8 Hours

Use only as directed.

NDC 21130-760-51

Arthritis Pain Relief

Compare to Tylenol® Arthritis Pain active ingredient†

Acetaminophen

Extended-Release Tablets, USP

Pain Reliever/Fever Reducer

- **For The Temporary Relief of Minor Arthritis Pain**

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

100 CAPLETS* 650 mg EACH

(* capsule-shaped tablets)

SAFEWAY™

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5089374/R1011

Lasts up to 8 Hours Use only as directed.

Arthritis Pain Relief

Acetaminophen

Extended-Release Tablets, USP
Pain Reliever/Fever Reducer
• For The Temporary Relief of Minor Arthritis Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

NDC 21130-760-51
Compare to Tylenol® Arthritis Pain active ingredient†



100 CAPLETS* 650 mg EACH (*capsule-shaped tablets)



Lasts up to 8 Hours Use only as directed.

Arthritis Pain Relief

Acetaminophen

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Pain Reliever/Fever Reducer
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Extended-Release Tablets, USP
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Compare to Tylenol® Arthritis Pain active ingredient†



100 CAPLETS* 650 mg EACH (*capsule-shaped tablets)



RD 12011

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.



Non Varnish Area

Drug Facts
Active ingredient (in each caplet) Acetaminophen USP 650 mg. Pain reliever/fever reducer.
Purpose
temporarily relieves minor aches and pains due to:
■ minor pain of arthritis ■ muscle aches
■ headache ■ common cold
■ menstrual and menstrual cramps
■ 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

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 have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets.
■ 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
■ the tablet got stuck in your throat.
■ pain gets worse or lasts more than 10 days
■ fever gets worse or lasts more than 3 days
■ you have trouble seeing, hearing, or feeling
■ 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.

Drug Facts (continued)
Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-342-7344).
Other information:
■ see end panel for batch number and expiration date

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 or
■ do not take more than 6 caplets in 24 hours
■ do not use for more than 10 days unless directed by a doctor

children under 18 years of age
■ 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

Inactive ingredients: croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polydioxanone, polyethylene glycol, polypropylene glycol, sodium lauryl sulfate, sodium lauryl ether sulfate, titanium dioxide

Questions? call 1-800-406-7184

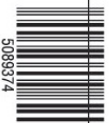
Contains No Aspirin

This product is not manufactured or distributed by McNeil Consumer Healthcare, Inc., owner of the registered trademark Tylenol® Arthritis Pain.
Keep the carton. It contains important information.

DISTRIBUTED BY SAFEMAX, INC.
P.O. BOX 4
PLEASANTON, CA 94566-0009
1-888-SAFEMAX / www.safemax.com

R1011

5089374



2 1/4 x 2 1/4 x 4

ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-760
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED 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:21130-760-51	100 in 1 BOTTLE		

Marketing Information

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

Labeler - Safeway Inc. (009137209)**Registrant** - Ohm Laboratories Inc. (051565745)**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(21130-760)