

**ARTHRITIS 8 HOUR- 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:
 - muscular aches
 - backache
 - headache
 - toothache
 - minor pain of arthritis
- 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 are allergic to acetaminophen or any of the inactive ingredients in this product.
- if you have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets.

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: 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 and children 12 years and over	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 12 years	do not use

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

8 Hour

Use only as directed.

NDC 21130-336-01

Pain Relief

Compare to Tylenol® 8 Hour active ingredient†

Acetaminophen

Extended-Release Tablets, USP

Pain Reliever/Fever Reducer

- For up to 8 Hour Relief of Minor Muscle Aches & Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

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

SAFEWAY®

DISTRIBUTED BY SAFEWAY INC.

5091297/R1011

Non Varnish Area

Batch No. _____

N
21130778021
8

Expiration Date: _____

5 1872 01 2012

This product is not manufactured or distributed by McNeil Consumer Healthcare, Inc., owner of the registered trademark Tylenol® 8 Hour.

8 Hour

Use only as directed.

Pain Relief

Acetaminophen

Extended-Release Tablets, USP
Pain Reliever/Fever Reducer

- For up to 8 Hour Relief of Minor Muscle Aches & Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

NDC 21130-336-01

Compare to
Tylenol® 8 Hour
active ingredient†

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

SAFEWAY

8 Hour

Use only as directed.

Pain Relief

Acetaminophen

Extended-Release Tablets, USP
Pain Reliever/Fever Reducer

- For up to 8 Hour Relief of Minor Muscle Aches & Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

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

SAFEWAY

Drug Facts (continued)

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)
- 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
- if you are taking other drugs, ask your doctor unless directed by a doctor
- ask a doctor

Children under 12 years

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, starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

Questions? Call 1-800-408-7884

Contains No Aspirin

Keep the carton. It contains important information.

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

DISTRIBUTED BY SAFEWAY INC.
P.O. BOX 99, PLEASANTON, CA 94566-0099
QUALITY & SATISFACTION GUARANTEED
OR YOUR MONEY BACK
1-888-SAFEWAY / www.safeway.com

R1011

Drug Facts

Active ingredient
Acetaminophen USP 650 mg.....Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - backache
 - headache
 - minor pain or arthritis
- 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 your doctor.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.
- if you have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets.

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
- you experience dizziness or lightheadedness
- these could be signs of a serious condition.

If present or feared, 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 (1-800-222-2222).

ARTHRITIS 8 HOUR

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-336
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:21130-336-01	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(21130-336)

Revised: 9/2012

Safeway Inc.