

TOPCO ARTHRITIS 8 HOUR - acetaminophen tablet, film coated, extended release
Topco Associates LLC

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
 - headache
 - minor pain of arthritis
 - backache

- 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.

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 and children 12 years and over	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
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 **1-888-423-0139**

PRINCIPAL DISPLAY PANEL

TopCare®

NDC 36800-228-01

FOR UP TO 8 HOUR RELIEF OF MINOR MUSCLE ACHES & PAIN

Lasts up to 8 - Hour

Pain Relief

ACETAMINOPHEN EXTENDED-RELEASE TABLETS, USP 650 mg

Pain Reliever/Fever Reducer

Use only as directed.

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

COMPARE TO TYLENOL® 8 HOUR active ingredient^{††}

100 CAPLETS[†] 650 mg EACH

(†CAPSULE-SHAPED TABLETS)

DISTRIBUTED BY TOPCO ASSOCIATES LLC

5095195/R512

TopCare®
FOR UP TO 8 HOUR RELIEF OF MINOR MUSCLE ACHES & PAIN
Lasts up to
8-Hour Pain Relief
ACETAMINOPHEN
EXTENDED-RELEASE TABLETS, USP 650 mg
Pain Reliever/Fever Reducer
Use only as directed.

actual size

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

COMPARE TO **TYLENOL® 8 HOUR** active ingredient††

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TopCare®
Lasts up to
8-Hour Pain Relief
ACETAMINOPHEN
EXTENDED-RELEASE TABLETS, USP 650 mg
Pain Reliever/Fever Reducer

Drug Facts (continued)
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 adults and children 12 years and over
- swallow whole – do not crush, chew, split or dissolve
- do not take more than 10 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor
- do not use

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, pregelatinized starch, polyethylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

Questions? call 1-888-423-0139

Contains No Aspirin

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

GLUTEN FREE
This TopCare® product is naturally gluten free. However, it may contain traces of gluten. For more information, please contact us at 1-888-423-0139.

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1-888-423-0139 ©TOPCO01/16/17, topcare@topco.com

Drug Facts

Active ingredient (in each caplet) Acetaminophen USP 650 mg,fever reducer

Purpose Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - cold/flu
 - headache
 - temporarily reduces fever
- minor pain of arthritis

Warnings

- 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
 - 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.

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 call a poison control center right away. (1-800-222-1222). Quick medical attention is critical.

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Non Varnish Area

Batch No. 01 36800134753

Expiration Date 3

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

TOPCO ARTHRITIS 8 HOUR
acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-228
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)	
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:36800-228-01	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 - Topco Associates LLC (006935977)**Registrant** - Ohm Laboratories Inc. (051565745)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(36800-228)

Revised: 8/2012

Topco Associates LLC