

TOPCARE 8 HR ARTHRITIS PAIN RELIEF- acetaminophen tablet, film coated, extended release

Topco Associates LLC

Topco Associates LLC. 8 HR Arthritis Pain Relief Drug Facts

Active ingredient (in each caplet)

Acetaminophen 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)
- meets the requirements of USP Dissolution Test 2

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-888-423-0139

Principal Display Panel

COMPARE TO TYLENOL® 8HR ARTHRITIS PAIN ACTIVE INGREDIENT

8 HR Arthritis Pain Relief

ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 mg

PAIN RELIEVER – FEVER REDUCER

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

8 HOUR

For the Temporary Relief of Minor Arthritis Pain

OUR PHARMACISTS RECOMMEND

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

actual size

150 CAPLETS† 650 mg EACH

†CAPSULE-SHAPED TABLETS

TopCare health™ NDC 36800-779-47
8HR Arthritis Pain Relief
 ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 mg
 PAIN RELIEVER • FEVER REDUCER
 For the Temporary Relief of Minor Arthritis Pain
 THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN
 150 CAPLETS† 650 mg EACH
 †CAPSULE-SHAPED TABLETS
 actual size
 OUR PHARMACISTS RECOMMEND
 DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN
 COMPARISON TO TYLENOL® 8HR ARTHRITIS PAIN ACTIVE INGREDIENT*
 DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING
 Pain relief/fever reducer
Drug Facts
 Active ingredient (in each caplet) Acetaminophen 650 mg
 Uses temporarily relieves minor aches and pains due to:
 ■ minor pain of arthritis ■ muscular aches ■ headache
 ■ menstrual and menstrual cramps ■ toothache
 ■ the common cold ■ headache
 ■ 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 redness ■ hives ■ rash
 ■ 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
 adults ■ do not take more than directed (see overdose warning)
 ■ 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
 ■ ask a doctor
 under 19 years of age
Other information ■ store at 20°-25°C (68°-77°F)
 ■ meets the requirements of USP Dissolution Test 2
Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose, polyethylene glycol, polyisobutyl methacrylate, polyvinylpyrrolidone, titanium dioxide
 Contains No Aspirin
 U.S. Patent 7,897,172
 *This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Tylenol® 8HR Arthritis Pain.
 Questions or comments? 1-888-423-0139
 DISTRIBUTED BY TOPCO ASSOCIATES LLC
 1500 N. WILSON AVE., SUITE 100
 GAITHERSBURG, MD 20878
 QUESTIONS? 1-888-423-0139
 topcare@topco.com www.topcarebrand.com
 Visit here for more information:
 http://topbrnds.com/48zv87
 GLUTEN FREE
 QUALITY GUARANTEED
 96647 88 F8
 76591 0092 0

TOPCARE 8 HR ARTHRITIS PAIN RELIEF			
acetaminophen tablet, film coated, extended release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-779
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L544
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-779-47	150 in 1 BOTTLE; Type 0: Not a Combination Product	04/12/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	04/12/2018	

Labeler - Topco Associates LLC (006935977)