

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

TopCare® health

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

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

actual size

150 CAPLETS† 650 mg EACH

†CAPSULE-SHAPED TABLETS



NDC 36800-779-47

COMPARE TO
TYLENOL® 8HR
ARTHRITIS PAIN
ACTIVE
INGREDIENT*

8HR Arthritis Pain Relief

ACETAMINOPHEN EXTENDED-RELEASE**TABLETS, 650 mg****PAIN RELIEVER • FEVER REDUCER****For the Temporary
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CONTAINING
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actual size

**150 CAPLETS[†]
650 mg EACH****†CAPSULE-
SHAPED
TABLETS****Drug Facts****DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING****Active ingredient (in each caplet)****Purpose**

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Uses

temporarily relieves minor aches and pains due to:

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- 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.

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Questions or comments? 1-888-423-0139Contains No Aspirin
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<http://topbrnds.com/4900in>*This product is not
manufactured or
distributed by Johnson &
Johnson Consumer Inc.,
distributor of Tylenol®
8HR Arthritis Pain.**GLUTEN FREE****✓QUALITY
GUARANTEED****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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (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)

