

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)
- **do not use if printed foil under cap is broken or missing**

- 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

8 HOUR

For the Temporary Relief of Minor Arthritis Pain

actual size

24 CAPLET† - 650 mg EACH

†CAPSULE-SHAPED TABLETS





8HR Arthritis Pain Relief

ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 mg
 PAIN RELIEVER • FEVER REDUCER



8 HOUR


For the Temporary Relief of Minor Arthritis Pain

actual size



24 CAPLETS[†] - 650 mg EACH

[†]CAPSULE-SHAPED TABLETS


 Scan here for more information or call 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC
 ELK GROVE VILLAGE, IL 60007
 © TOPCO PHARMA
 QUESTIONS? 1-888-423-0139
 www.topcarebrand.com

Drug Facts (continued)

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

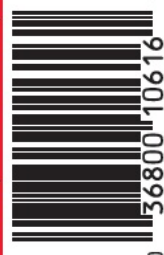
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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.

Contains No-Aspirin U.S. Patent 7,897,172

 0 36800 10616 1
 GOLD-ARTRIA
 54462 88 C 10

Drug Facts (continued)

Directions

- 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

under 18 years of age

Other information

- store at 20-25°C (68-77°F)
- do not use if printed foil under cap is broken or missing
- meets the requirements of USP *Dissolution Test 2*

Inactive ingredients camellia wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, malto-dextrin, microcrystalline cellulose, polyethylene glycol, polyacrylate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments? -888-423-0139

Drug Facts (continued)

Active ingredient
(in each caplet)
Acetaminophen 650 mg.....Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual 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 redness
- hives
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Drug Facts (continued)

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.

TOPCARE 8 HR ARTHRITIS PAIN RELIEF acetaminophen tablet, film coated, extended release			
Product Information	Product Type	Item Code (Source)	HUMAN OTC DRUG 54462 88 C 10 NDC:36800-455

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: 70097M6I30)	
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:36800-455-78	1 in 1 CARTON	07/10/2018	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-455-62	1 in 1 CARTON	07/10/2018	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:36800-455-71	1 in 1 CARTON	07/10/2018	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:36800-455-79	1 in 1 CARTON	10/16/2019	
4		400 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	07/10/2018	

Labeler - Topco Associates LLC (006935977)

Revised: 4/2022

Topco Associates LLC