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

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	 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	• 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?

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

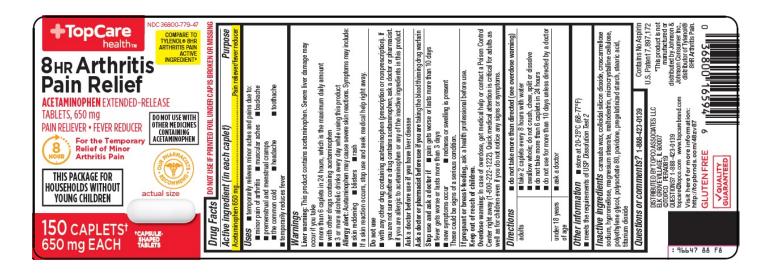
OUR PHARMACISTS RECOMMEND

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

actual size

150 CAPLETS† 650 mg EACH

†CAPSULE-SHAPED TABLETS



TOPCARE 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		

ı	Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength	
ı	ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	650 mg	
ı				

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
PO VIDO NE (UNII: FZ989 GH94E)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

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

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:36800-779-47	150 in 1 BOTTLE; Type 0: Not a Combination Product	0 4/12/20 18	

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)

Revised: 11/2019 Topco Associates LLC