HARRIS TEETER ARTHRITIS PAIN- acetaminophen tablet, film coated, extended release Harris Teeter, LLC

Harris Teeter, LLC Arthritis Pain 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)
- 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?

1-800-719-9260

Principal Display Panel

Arthritis Pain

Compare to the active ingredient in Tylenol® 8HR Arthritis Pain

Acetaminophen Extended-Release Tablets, 650 mg

PAIN RELIEVER/FEVER REDUCER

For the Temporary Relief of Minor Arthritis Pain

Push & Turn Cap

50 CAPLETS* - 650 mg EACH

*Capsule-Shaped Tablets

Actual Size



active ingredient in Tyleno[®] 8HR Arthritis Pain

Arthritis Pain

Acetaminophen Extended-Release Tablets, 650 mg

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Combins No Aspirin

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Do not use

■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains a cetamin ophen, ask a doctor or

Drug Facts (continued)

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

Stopuse and ask a doctor if

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- fever gets worse or lasts more than 3 days
- new symptomsoccur
- rednessor swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional

Keep out of reach of children.

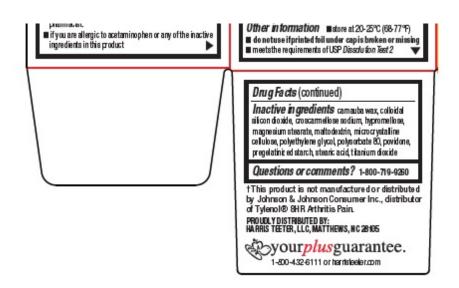
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ofage



HARRIS TEETER ARTHRITIS PAIN

acetaminophen tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-544
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	650 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

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

Contains

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:69256-544-71	1 in 1 CARTON	11/21/2015		
l	1	50 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	11/21/2015	

Labeler - Harris Teeter, LLC (048463103)

Revised: 12/2019 Harris Teeter, LLC