8 HOUR PAIN RELIEF- acetaminophen tablet, film coated, extended release HyVee Inc

Hy-Vee, Inc. 8 Hour 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:
- muscular aches
- backache
- headache
- minor pain of arthritis
- 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

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 and children 12 years and over	 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
children under 12 years	• do not use

Other information

- store at 20°-25°C (68°-77°F). Avoid excessive heat 40°C (104°F).
- see end panel for lot number and expiration date

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C red #40 aluminum lake, 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

Headache/Backache

Minor Pain of Arthritis

Compare to Tylenol® 8 HR active ingredient

8 HOUR PAIN RELIEF

Acetaminophen Extended-Release Tablets, 650 mg

Pain Reliever-Fever Reducer

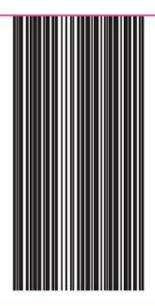
FOR UP TO 8 HOUR RELIEF OF MINOR MUSCLE ACHES AND PAIN

Actual Size

650 mg EACH

*capsule-shaped tablets





cetaminophen Extended-Release Tablets, 650

Headache/Backache Minor Pain of Arthritis

NDC 42507-217-78

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 650 mg......Pain reliever/fever reducer

Purpose

٠

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - backache
 - headache
 - minor pain of arthritis
- 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

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

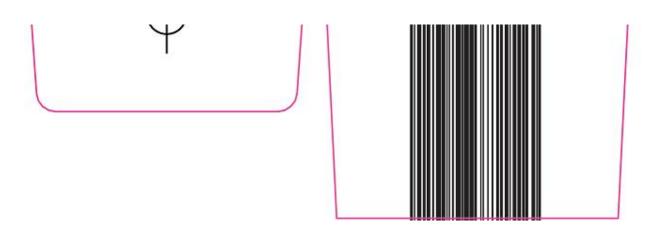
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

Actual Size 100 CAPLETS*- 650 mg EACH *capsule-shaped tablets Pain Reliever • Fever Reducer RELIEFOF







8 HOUR PAIN RELIEF

acetaminophen tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:42507-217
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	650 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX		
SILICON DIO XIDE		
CROSCARMELLOSE SODIUM		
HYPROMELLOSES		
MAGNESIUM STEARATE		
MALTODEXTRIN		
CELLULOSE, MICRO CRYSTALLINE		
POLYETHYLENE GLYCOLS		
POLYSORBATE 80		
POVIDONES		
STEARIC ACID		
TITANIUM DIO XIDE		

Product Characteristics			
Color	RED	Score	no score
Shape	CAPSULE	Size	19 mm
Flavor		Imprint Code	L217
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-217-71	1 in 1 CARTON		
1		50 in 1 BOTTLE		
2	NDC:42507-217-78	1 in 1 CARTON		
2		100 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075077	09/23/2005		

Labeler - HyVee Inc (006925671)

Revised: 12/2012 HyVee Inc