

SUNMARK PAIN RELIEVER- acetaminophen tablet, film coated, extended release

Strategic Sourcing Services LLC

McKesson Pain Reliever 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
- minor pain of arthritis
- toothache
- premenstrual and menstrual cramps
- headache
- the common cold
- 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 and children 12 years and over	<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
children under 12 years	<ul style="list-style-type: none"> • do not use

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

Package/Label Principal Display Panel

COMPARE TO TYLENOL® 8HR ACTIVE INGREDIENT

pain reliever

Acetaminophen Extended-Release Tablets, 650 mg

Pain reliever/Fever reducer

For up to 8 Hours Relief of Minor Muscle Aches and Pain

Actual Size

100 CAPLETS* - 650 mg EACH

GLUTEN FREE

*Capsule-Shaped Tablets



SUNMARK PAIN RELIEVER

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0017
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:70677-0017-1	1 in 1 CARTON	05/30/2017	
1		100 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		05/30/2017	

Labeler - Strategic Sourcing Services LLC (116956644)