SUNMARK PAIN RELIEVER- acetaminophen tablet, film coated Strategic Sourcing Services LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

McKesson Pain Reliever Drug Facts

Active ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- the common cold
- headache
- backache
- minor pain of arthritis
- toothache
- muscular aches
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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 have ever had an allergic reaction to this product or any of its ingredients

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 tablets every 6 hours while symptoms last do not take more than 6 tablets in 24 hours, unless directed by a doctor do not use for more than 10 days unless directed by a doctor
Children under 12 years	ask a doctor

Other information

• store at 20-25°C (68-77°F)

Inactive ingredients

corn starch, FD&C red #40 aluminum lake, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

COMPARE TO EXTRA STRENGTH TYLENOL® ACTIVE INGREDIENT

pain reliever

Extra Strength

Pain reliever & Fever reducer

Easy to Swallow – Adults

Acetaminophen

Actual Size

GLUTEN FREE

100 TABLETS 500 mg EACH



SUNMARK PAIN RELIEVER

acetaminophen tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0093	
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	500 mg	

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics			
Color	RED	Score	no score
Shape	ROUND (CONVEX)	Size	11mm
Flavor		Imprint Code	L31G
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0093-2	1 in 1 CARTON	0 1/22/20 20	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70677-0093-1	1 in 1 CARTON	0 1/22/20 20	
2		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
OTC monograph not final	part343	01/22/2020	

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 1/2020 Strategic Sourcing Services LLC