SUNMARK PAIN RELIEVER EXTRA STRENGTH- acetaminophen tablet
Praxis, LLC

Sunmark Pain Reliever Drug Facts

Active ingredient (in each caplet)

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 caplets every 6 hours while symptoms last • do not take more than 6 caplets 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 20-25ºC (68-77ºF)

Inactive ingredients

carnauba wax, corn starch*, croscarmellose sodium*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid

*may contain one or more of these ingredients

Questions or comments?

1-800-719-9260

Principal Display Panel

COMPARE TO EXTRA STRENGTH TYLENOL® ACTIVE INGREDIENT

pain reliever

Extra Strength

Pain reliever/Fever reducer

Adults

Acetaminophen

Actual Size

50 CAPLETS 500 mg EACH

GLUTEN FREE

SUNMARK PAIN RELIEVER EXTRA STRENGTH

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59368-225
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	L484
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-225-03	1 in 1 CARTON	08/11/2003	06/01/2025
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59368-225-01	1 in 1 CARTON	08/11/2003	05/01/2025
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59368-225-02	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2003	06/01/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/11/2003	06/01/2025

Labeler - Praxis, LLC (016329513)

Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-225) , pack(59368-225) , label(59368-225)