

**EXTRA STRENGTH ACETAMINOPHEN- acetaminophen tablet**  
**Spirit Pharmaceutical LLC**

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**Dr. Juan's Santo Remedio**

**EXTRA STRENGTH ACETAMINOPHEN**

***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 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"> <li>▪ take 2 caplets every 6 hours while symptoms last</li> <li>▪ do not take more than 6 caplets in 24 hours, unless directed by a doctor</li> <li>▪ do not use for more than 10 days unless directed by a doctor</li> </ul>
children under 12 years	ask a doctor

**Other information**

- **each caplet contains:** magnesium 0.43 mg
- store between 20-25°C (68-77°F)
- **do not use if carton is opened or inner Safety Seal is broken or missing**

**Inactive ingredients**

Hypermellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol,

polyvinylpyrrolidone, pregelatinized starch, stearic acid, talc, titanium dioxide

**Questions or comments?**

**1-855-736-3346**

**PRINCIPAL DISPLAY PANEL**

COMPARE TO EXTRA STRENGTH TYLENOL® ACTIVE INGREDIENT\*

Dr. Juan's

Santo Remedio

PARA EL

DOLOR

Para el Dolor / Bajar La Fiebre

No Contiene Aspirina

Acetaminofén Extra Fuerte

Acetaminophen Extra Strength

Pain Reliever / Fever Reducer / Contains No Aspirin

500 MG · 100 CAPLETAS/CAPLETS



## EXTRA STRENGTH ACETAMINOPHEN

acetaminophen tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-6113
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
<b>HYPROMELLOSE 2208 (15000 MPA.S)</b> (UNII: Z78RG6M2N2)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	S500
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-6113-1	1 in 1 CARTON	04/06/2020	
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
OTC Monograph Drug	M013	04/06/2020	

**Labeler** - Spirit Pharmaceutical LLC (179621011)

Revised: 12/2023

Spirit Pharmaceutical LLC