

**EXTRA STRENGTH PAIN RELIEF- acetaminophen tablet, film coated**  
**Spirit Pharmaceuticals LLC**

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**Extra Strength Pain Relief**

***Drug Facts***

***Active ingredients (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 non prescription). 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)

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adults & children 12 years & over	<ul style="list-style-type: none"><li>• take 2 tablets every 6 hours while symptoms last</li><li>• do not take more than 6 tablets 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

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### ***Other information***

- store between 20-25°C (68-77°F)

### ***Inactive Ingredients***

Hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, stearic acid, talc, titanium dioxide

### ***Questions or comments?***

**1-888-333-9792**

### **Principal Display Panel**

Compare to Extra Strength Tylenol® Caplets active ingredient†

Extra Strength pain relief

acetaminophen 325 mg - pain reliever / fever reducer

40 Caplets



## EXTRA STRENGTH PAIN RELIEF

acetaminophen tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4211
<b>Route of Administration</b>	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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<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:68210-4211-4	1 in 1 CARTON	08/22/2022	
1		40 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	08/22/2022	

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

Revised: 12/2023

Spirit Pharmaceuticals LLC