# PAIN RELIEVER AND FEVER REDUCER- acetaminophen tablet, film coated Spirit Pharmaceuticals LLC

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Pain Reliever and Fever Reducer

#### **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

## Warning

**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 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 & children 12 years & over	<ul> <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

#### Other information

• store between 20-25°C (68-77°F)

## Inactive ingredients

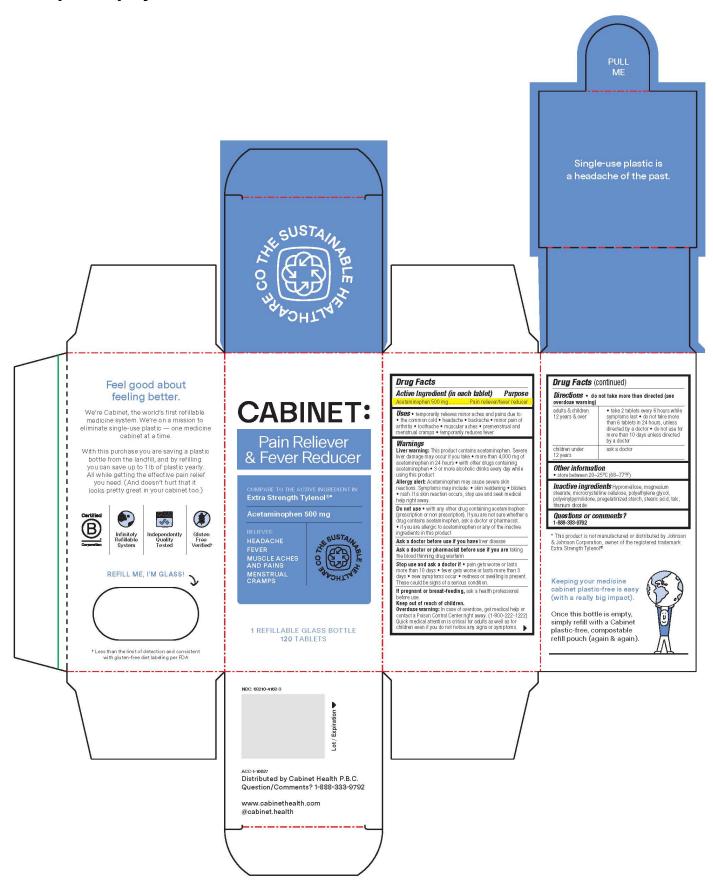
Hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl pyrrolidone, pregelatinized starch, stearic acid, talc, titanium dioxide

# Inactive ingredients

1-888-333-9792

# Distributed by:

## **Principal Display Panel**



# PAIN RELIEVER AND FEVER REDUCER

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4225
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
	Ingredient Name	<b>Basis of Strength</b>	Strength
	ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients		
Ingredient Name	Strength	
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	S500
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4225- 1	120 in 1 JAR; Type 0: Not a Combination Product	11/15/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/15/2022	

Revised: 12/2024 Spirit Pharmaceuticals LLC