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

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	 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 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:

Cabinet Health P.B.C.

Principal Display Panel





CABINET:

Pain Reliever & Fever Reducer Refill

COMPARE TO THE ACTIVE INGREDIENT IN:

Extra Strength Tylenol®*

Acetaminophen 500 mg

RELIEVES:

HEADACHE · FEVER · MUSCLE ACHES AND PAINS MENSTRUAL CRAMPS



TO OPEN:

- 1. POSITION THUMBS INSIDE THE SHORT FLANGE OVER THE LOCKS.
- 2. GRIP WHILE PIVOTING THUMBS OUTWARD TO OPEN THE LOCKS.

Tamper evident: do not use if pouch is open

Drug Facts

Active Ingredient (in each tablet)

Purpose

Acetaminophen 500 mg......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)

adu	lts -	&	ch	ildr	en
121	/ea	rs	&	ove	er

• 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 vears

ask a doctor

Drug Facts (continued)

Other Information

• store between 20-25°C (68-77°F)

Inactive ingredients Hypermellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments? 1-888-333-9792

Single-use plastic is a headache of the past.

- * This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol®
- † Less than the limit of detection and consistent with gluten-free diet labeling per FDA

Distributed by: Cabinet Health P.B.C. Question/Comments? 1-888-333-9792 www.cabinethealth.com

Lot / Expiration ▼









PAIN RELIEVER AND FEVER REDUCER

acetaminophen tablet, film coated

B			
Prodi	CT	Inform	ation
I I Out			ation

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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: FZ 989GH94E)	
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:68210-4235-1	120 in 1 POUCH; Type 0: Not a Combination Product	11/17/2022	

Marketing Information

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

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2024 Spirit Pharmaceuticals LLC