

SOUND BODY EXTRA STRENGTH PAIN RELIEVER- acetaminophen 500 mg tablet

Allegiant Health

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SoundBody Extra Strength Pain Reliever

Active ingredient (in each caplet)

Acetaminophen 500mg

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 4,000mg 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

the user is 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

- You may report side effects to 1-888-952-0050

If pregnant or breast-feeding.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Keep out of reach of children. Overdose warning: In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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 8 caplets in 24 hours, unless directed by a doctor
- do not take for more than 10 days unless directed by a doctor

Children under 12 years of age: ask a doctor

Other information

- store between 20°-25°C (68°-77°F)
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

corn starch, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-888-952-0500

Principal Display Panel

SOUNDBODY™

Compare to the Active Ingredient in Tylenol® Caplets*

EXTRA STRENGTH

See New Warnings Information

Pain Reliever

Acetaminophen 500mg

Pain Reliever/Fever Reducer

100 Caplets

(pill image) Actual Size

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol®.

Distributed by:

Allegiant Health

Deer Park, NY 11729

V#5003620 ITEM#FP0638

LB1299

R0617

Pain Relief EX 100ct. Caplets



SOUNDBODY™

EXTRA STRENGTH

Pain Reliever

Acetaminophen 500 mg

Pain Reliever-Fever Reducer

100 CAPLETS

See New Warnings Information

USE ONLY IF IMPRINTED SEAL UNDER CAP IS INTACT

SEE CARTON FOR COMPLETE INFORMATION

Drug Facts

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Acetaminophen 500mg.....Pain reliever/fever reducer

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Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000mg of acetaminophen in 24 hours or 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. **Do not use** 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 have** taken 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. **Keep out of reach of children.** **Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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 8 caplets in 24 hours, unless directed by a doctor.** **do not take for more than 10 days, unless directed by a doctor.** Children under 12 years of age: ask a doctor

Distributed by:
Allegiant Health
Deer Park, NY 11729
V#5003620 ITEM#P0638

Lot: Exp:

LB1298
R0617

Pain Relief EX 100ct. Caplets

SOUND BODY EXTRA STRENGTH PAIN RELIEVER

acetaminophen 500 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 168-9 13
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
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	AZ012
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-913-01	1 in 1 CARTON	12/17/2014	
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 NOT FINAL	part343	12/17/2014	

Labeler - Allegiant Health (079501930)

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Allegiant Health