

COLD TABS II- acetaminophen, guaifenesin and phenylephrine hcl tablet
ADVANCED FIRST AID, INC.

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.

ACTIVE INGREDIENT IN EACH TABLET-

Acetaminophen 325 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

pain reliever/fever reducer

expectorant

decongestant

Uses: temporarily: • relieves nasal congestion associated with sinusitis • relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies • relieves sinus congestion and pressure, helps decongest sinus openings and passages • restores free breathing • helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive. temporarily relieves minor aches, pains, and fever associated with: • headache • common cold • toothache • backache • muscular aches • menstrual cramps

Warnings:

Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if: • you take more than 8 tablets in 24 hours • you take with other drugs containing acetaminophen (prescription or non-prescription) • you have 3 or more alcoholic drinks every day while using this product

Do not use: • with any other product containing acetaminophen this will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns. • more than the recommended dose • for more than 10 days for pain unless directed by a doctor • for more than 3 days for fever unless directed by a doctor • when using this product do not exceed recommended dose • if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping MAOI drug. If you do not know if your prescription drug contains an MAOI, consult a doctor or pharmacist before taking this product.

Stop use and ask a doctor if: • symptoms do not improve • pain or fever persists or gets worse • new symptoms occur • redness or swelling is present • nervousness, dizziness or sleeplessness occur • symptoms do not improve within 7 days or are accompanied by fever cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache.

Ask a doctor before use if you have: • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate gland • persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema or where cough is accompanied by excessive phlegm (mucus)

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

KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions:

Adults and children 12 years of age and older: Take 2 tablets every 4 to 6 hours or as needed, do not exceed 8 tablets in 24 hours, or as directed by a doctor.

Children under 12 years: Consult a doctor.

Inactive Ingredients: FD&C Red #40, microcrystalline cellulose, povidone, sodium starch glycolate, starch, and stearic acid.



Product #1254

250 Tablets • 2 Tablets Per Packet

Product #1254

Drug Facts	Purpose
Active ingredients (in each tablet)	pain reliever/fever reducer
Acetaminophen 325 mg	expectorant
Guafenesin 200mg	Decongestant
Phenylephrine HCl 2 mg	
Uses: temporarily • relieves nasal congestion associated with sinusitis • relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies • relieves sinus congestion and pressure. Helps dislodge sinus openings and passages • restores freer breathing • helps loosen phlegm (mucus) and thin bronchial secretions to aid the bronchial passage of mucus from the lungs, and make cough more productive.	
Warnings:	
Live Warning: This product contains Acetaminophen. Severe liver damage may occur if: • you take more than 8 tablets in 24 hours • you take with other drugs containing acetaminophen (prescription or over-the-counter) • you take 1 or more tablets every hour using this product.	
Allergy Warning: acetaminophen may cause severe skin reactions. Symptoms may include: • skin rash/ hives • blisters • sores • if a skin reaction occurs, stop use and seek medical help right away.	
Do not use: • with any other product containing acetaminophen this will provide more than the recommended dose (excess of acetaminophen could cause serious health concerns • more than the recommended dose • for more than 10 days for pain unless directed by a doctor • for more than 3 days for fever unless directed by a doctor unless using this product do not exceed recommended dose • if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping MAOI drug. If you do not know if your prescription drug contains an MAOI, consult a doctor or pharmacist before taking this product.	
Ask a doctor or pharmacist before use (if): • you are taking the blood thinning drug warfarin.	
Stop use and ask a doctor if: • symptoms do not improve • pain or fever persists or gets worse • new symptoms occur • redness or swelling is present • neurosis, dizziness or sleepiness occur • symptoms do not improve within 5 days or are accompanied by fever • cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache.	
Ask a doctor before use if you have: • liver disease • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate gland • persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema or where cough is accompanied by excessive phlegm (mucus).	
If pregnant or breast-feeding baby, ask a health professional before use. KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	
Directions: Adults and children 12 years of age and older: • Take 2 tablets every 4 to 6 hours as needed, do not exceed 8 tablets in 24 hours, or as directed by a doctor. Children under 12 years: • consult a doctor.	
Other information: • Tamper Evident. Do not use if packet is torn, cut or opened. • Store at controlled room temperature 15° to 30° C (59° to 86°F). • Avoid excessive heat and humidity.	
Inactive Ingredients: FD&C Red #40, methylcellulose, microcrystalline cellulose, povidone, sodium starch glycolate, starch, and stearic acid.	



Cold Tabs II

PULL TO OPEN



Cold Tabs II

Acetaminophen | Pain Reliever/Fever Reducer
Guafenesin | Expectorant
Phenylephrine | Decongestant

Helps reduce congestion, sinus pain and pressure, cough, fever, and pain.

Non-drowsy, Aspirin and Ephedrine Free formula



Cold Tabs II

- Helps reduce congestion, sinus pain and pressure, cough, fever, and pain.
- Non-drowsy, Aspirin and Ephedrine Free formula

Do not use if individual packet is open or torn.

250 Tablets • 2 Tablets Per Packet

Manufactured for:
Advanced First Aid, Baltimore, MD 21237
www.advanced1staid.com • 1-888-922-5878



TAMPER EVIDENT: DO NOT USE IF PACKET IS TORN OR CUT.



Each tablet contains:
Acetaminophen 325 mg.
Guaifenesin 200 mg.
Phenylephrine HCl 5 mg.
2 TABLETS PER PACKET

USES: For temporary relief of minor aches, pains, headaches, and nasal congestion associated with sinusitis, hay fever or other respiratory allergies. Promotes nasal and/or sinus drainage. **WARNINGS: Liver Warning:** This product contains Acetaminophen. Severe liver damage may occur if you take more than 8 tablets in 24 hours with other drugs containing acetaminophen (prescription or non-prescription) or 3 or more alcoholic drinks every day while using this product. Ask a doctor before use if you have heart disease, high blood pressure, diabetes, or liver disease. **KEEP OUT OF REACH OF CHILDREN.** In case of overdose, get medical help or contact a Poison Control Center right away. **DIRECTIONS:** Adults: 2 tablets every 4 to 6 hours, not to exceed 8 tablets in any 24 hour period. Children under 12 years: ask a doctor. Store at controlled room temperature 15° to 30°C (59° to 86°F). **Additional Warnings/Cautions:** See Box. **Mfg. for:** Advanced First Aid, Baltimore, MD 21237
American Safety & First Aid Osceola, IN 46561

acetaminophen, guaifenesin and phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67060-106
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	pink (ROSE PINK)	Score	no score
Shape	ROUND	Size	12mm
Flavor	CHERRY	Imprint Code	FR8
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67060-106-68	100 in 1 CARTON	04/10/2015	
1	NDC:67060-106-02	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/10/2015	

Labeler - ADVANCED FIRST AID, INC. (114477180)

Registrant - ADVANCED FIRST AID, INC. (114477180)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	pack(67060-106)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA TAB LABORATORIES, INC.		151051757	manufacture(67060-106)

Revised: 10/2016

ADVANCED FIRST AID, INC.