

**DECONGESTANT II- 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.*

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**ACTIVE INGREDIENT (IN EACH TABLET)-** Phenylephrine HCl 5 mg

Nasal 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 freer breathing through the nose

**Warnings:**

**Do not use: • more than the 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
- 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

**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

**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:** croscarmellose sodium, D&C Red #27 lake, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, starch, stearic acid

Descongestionante Nasal y Sinusitis

**Decongestant II**

Nasal & Sinus

Product #1264

**250** Tablets • 2 Tablets Per Packet

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**Drug Facts**

**Active Ingredient (in each tablet)** ..... **Purpose**  
Phenylephrine HCl 5 mg ..... Nasal Decongestant

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**Other information:**

- Each tablet contains: Calcium 10mg
- 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:** croscarmellose sodium, D&C Red #27 Ink, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, starch, stearic acid.

Nasal & Sinus

**Decongestant II**

Phenylephrine HCL - Nasal Decongestant  
Descongestionante Nasal y Sinusitis

PULL TO OPEN

Do not use if individual packet is open or torn.

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 Tablets • 2 Tablets Per Packet

Descongestionante Nasal y Sinusitis

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**Descongestionante Nasal y Sinusitis**

• Helps reduce nasal and sinus congestion and pressure.  
• Helps restore freer breathing through the nose.

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

PACKAGED IN THE USA

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<h2 style="margin: 0;">Product Information</h2>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67060-333

Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5

### Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	FR4
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67060-333-68	100 in 1 CARTON	04/09/2015	
1	NDC:67060-333-02	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:67060-333-67	250 in 1 CARTON	04/09/2015	
2	NDC:67060-333-02	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	04/09/2015	

Labeler - ADVANCED FIRST AID, INC. (114477180)

Registrant - ADVANCED FIRST AID, INC. (114477180)

### Establishment

Name	Address	ID/FEI	Business Operations
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ULTRA SEAL CORPORATION		085752004	pack(67060-333)
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## Establishment

Name	Address	ID/FEI	Business Operations
ULTRA TAB LABORATORIES, INC.		151051757	manufacture(67060-333)

Revised: 8/2019

ADVANCED FIRST AID, INC.