

**KLERNAZ- guaifenesin, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet**  
**Pharma Associate Consultants, 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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**Klernaz Tablets**

**Drug Facts**

**Active ingredient**

Dextromethorphan HBr 15 mg

Guaifenesin 400 mg

Phenylephrine HCL 10 mg

**Purpose**

Cough Suppressant

Expectorant

Nasal Decongestant

**Uses:** temporarily relieves these symptoms occurring with a cold nasal congestion: cough due to minor throat and bronchial irritation

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.

**Warnings:**

- **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
- 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. A persistent cough may be a sign of a serious condition.

**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)

**Directions:**

**Adults and children 12 years of age and older**

- Take 1 tablet every 4-6 hours as needed, do not exceed 4 tablets in 24 hours, or as directed by a doctor.

**Children 6-12 years :**

- Take 1/2 tablet every 4-6 hours as needed, do not exceed 2 tablets in 24 hours, or as directed by a doctor.

**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 children even if you do not notice any signs or symptoms.

Colloidal Silicon Dioxide, F&C Blue # 2, Microcrystalline Cellulose, Stearic Acid

**Other information:**

- Do not use if there are signs of tampering
- Store at Controlled Room Temperature 15°-30°C (59°-86°F)

**PAC**

Pharma Associate

Consulting, LLC

Guntersville, AL 35976

**Principal Display Panel - 30 Tablets Bottle Labeling**

NDC 69140-0620-03

**Klernaz**

**TABLETS**

**TRIPLE COMBINATION RELIEF:**

**Expectorant: Guaifenesin 400MG**

**Decongestant: Phenylephrine HCL 10MG**

**Cough Suppressant: Dextromethorphan HBR 15MG**

**30 Tablets**

**Drug Facts**

**Active ingredient:** Dextromethorphan Hbr 15 mg, Guaifenesin 400 mg, Phenylephrine HCL 10 mg

**Purpose:** Cough Suppressant, Expectorant, Nasal Decongestant

**Uses:** temporarily relieves these symptoms occurring with a cold: nasal decongestion; cough due to minor throat and bronchial irritation; helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.

**Warnings:** 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 drugs, 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 or 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. A persistent cough may be a sign of a serious condition.

**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).

**Directions:** Adults and children 12 years of age and older: Take 1 tablet every 4-6 hours as needed, do not exceed 4 tablets in 24 hours, or as directed by a doctor. Children 6-12 years: Take 1/2 tablet every 4-6 hours as needed, do not exceed 2 tablets in 24 hours, or as directed by a doctor.

**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.

**Inactive ingredients:** Colloidal Silicon Dioxide, F&C Blue # 2, Microcrystalline Cellulose, Stearic Acid

**Other information:** Do not use if there are signs of tampering. Store at Controlled Room Temperature 15°-30° C (59°- 86°F).

**PAC Pharma Associate Consulting, LLC Guntersville, AL 35976**

**Lot:**   
**Exp:**

**KLERNAZ**

guaifenesin, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69 140-620
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>COLLOIDAL SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

**Product Characteristics**

<b>Color</b>	blue (Light Blue)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69 140-620-03	30 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	08/07/2015	

**Labeler** - Pharma Associate Consultants, Inc (079418551)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
TG United		172837085	manufacture(69 140-620)