

AQUANAZ- dextromethorphan hydrobromide, guaifenesin and phenylephrine hydrochloride tablet

Capital Pharmaceutical, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Aquanaz Tablets

Aquanaz Drug Facts.

Active Ingredient.

Dextromethorphan HBr 15mg.

Purpose.

Cough Suppressant.

Active Ingredient.

Guaifenesin 400mg.

Purpose.

Expectorant.

Active Ingredient.

Phenylephrine HCL 10mg.

Purpose.

Nasal Decongestant.

Uses:

Temporally relieves these symptoms accruing with a cold nasal decongestion cough due to minor throat and bronchial irritation—helps loosen phlegm (mucus) and thins 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--new symptoms occur--redness or swelling is present--nervousness, dizziness or sleeplessness occurs--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 fever, rash or persistent headache. A persistent cough may be the 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 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 ½ 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 care 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.

Inactive Ingredients:

F&C Blue #2 Microcrystalline Cellulose, Silicone Dioxide, Stearic Acid.

Other Information:

Do not use if there are signs of tampering—Store at controlled room temperature 15deg-30degC (59-86degF)

PRINCIPAL DISPLAY PANEL

NDC 29978-587-01

NEW

Aquanaz

TABLETS

TRIPLE COMBINATION RELIEF:

Cough Suppressant: Dextromethorphan HBR 15 MG

Expectorant: Guaifenesin 400 MG

Decongestant: Phenylephrine HCL 10 MG

100 Tablets

Drug Facts

Active ingredient	Purpose
Dextromethorphan HBr 15 mg	Cough Suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCL 10 mg	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

NEW

Aquanaz

TABLETS

TRIPLE COMBINATION RELIEF:

Cough Suppressant: Dextromethorphan HBR 15 MG

Expectorant: Guaifenesin 400 MG

Decongestant: Phenylephrine HCL 10 MG

100 Tablets

Drug Facts (Continued)

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

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

Distributed by:
Capital Pharmaceuticals, LLC.
Powell, OH 43065

AQUANAZ

dextromethorphan hydrobromide, guaifenesin and phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29978-587
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	blue (light blue)	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	PAC3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29978-587-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/10/2015	

Labeler - Capital Pharmaceutical, LLC (831545541)

Revised: 11/2024

Capital Pharmaceutical, LLC