QUENALIN COUGH - diphenhydramine hydrochloride syrup
Qualitest Pharmaceuticals, 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.

Quenalin Cough Syrup

Active Ingredient: Diphenhydramine hydrochloride 12.5 mg (in each 5 mL(teaspoonful)(TSP))

Purpose: Antitussive

Uses

temporarily relieves cough due to cold or bronchial irritation

Warnings

Do not use with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- cough accompanied by excessive phlegm (mucus)
- breathing problems such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use

if you are taking tranquilizers or sedatives

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

symptoms last for more than 1 week or recurred or accompanied by fever, rash, headache

If pregnant or breast-feeding

- ask 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.

Directions

Do not take more than six doses

Adults and children over 12 years	2 teaspoonfuls(TSP) every 4 hours

children under 12 years	DO NOT USE

Use only with supplied dosage cup

Other information

- Store at room temperature 20°-25°C (68°-77°F)
- Protect from freezing.

Inactive ingredients:

Alcohol 5%, ammonium chloride, citric acid, D&C red no. 33, FD&C red no. 40, menthol, methylparaben, propylene glycol, propylparaben, sodium citrate, strawberry flavor, sucrose, water

Made in
USA
for QUALITEST PHARMACEUTICALS
130 VINTAGE DRIVE
HUNTSVILLE, AL 35811

NDC 0603-0860-54

Quenalin
Cough Syrup

(Diphenhydramine Hydrochloride)
Contains 5% Alcohol

Cough Suppressant
Cough Due to Colds
For Children & Adults

4 FL OZ (118 mL)

DO NOT USE IF TAMPER-EVIDENT SEAL OVER CAP IS BROKEN OR MISSING

Active ingredient (in each 5 mL (teaspoonful)(TSP)) **Purpose**
Diphenhydramine hydrochloride 12.5 mg ..... Antitussive

Uses temporarily relieves cough due to cold or bronchial irritation

Warnings
Do not use with any other product containing diphenhydramine, even one used on skin
Ask a doctor before use if you have ■ glaucoma ■ cough accompanied by excessive phlegm (mucus) ■ breathing problems such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives
When using this product ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ excitability may occur, especially in children ■ be careful when driving a motor vehicle or operating machinery
Stop use and ask a doctor if symptoms last for more than 1 week or recurred or accompanied by fever, rash, headache
If pregnant or breast-feeding, ask health professional before use.
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Made in the **USA**
for Qualitest Pharmaceuticals
130 Vintage Drive
Huntsville, AL 35811

Rev. 11/12

N 3 0603-0860-54 7

QUENALIN COUGH

diphenhydramine hydrochloride syrup

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:0603-0860
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Diphenhydramine hydrochloride (Diphenhydramine)	Diphenhydramine hydrochloride	12.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Alcohol	
ammonium chloride	
anhydrous citric acid	
D&C red no. 33	
FD&C red no. 40	
menthol	
methylparaben	
propylene glycol	
propylparaben	
sodium citrate	
sucrose	
water	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	STRAWBERRY (Strawberry Flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0603-0860-54	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/03/1993	

Labeler - Qualitest Pharmaceuticals, Inc (011103059)

Revised: 12/2013 Qualitest Pharmaceuticals, Inc