GUAIFENESIN AND CODEINE PHOSPHATE- guaifenesin and codeine phosphate solution
QUAGEN PHARMACEUTICALS LLC

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.

Guaifenesin and Codeine Phosphate Oral Solution, USP CV
100 mg/10 mg per 5 mL

Drug Facts

Active ingredients (in each 5 mL = 1 tsp)	***Purpose***
Codeine phosphate, USP 10 mg	Cough suppressant
Guaifenesin, USP 100 mg	Expectorant

Uses

- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
- your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

Ask your doctor before use if

- you have a persistent cough, this may be a sign of a serious condition
- you have a persistent cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- you have a cough that is accompanied by excessive phlegm (mucus)
- you have chronic pulmonary disease or shortness of breath
- giving to a child who is taking other drugs

When using this product

- giving a higher dose than recommended by a doctor could result in serious side effects for your child. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age.
- may cause or aggravate constipation

Stop use and ask a doctor if

- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms of a serious condition.

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

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- Do not exceed 6 doses in 24 hours.

Adults and children 12 years of age and over:	2 tsp (10 mL) every 4 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 tsp (5 mL) every 4 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

Other information

Each tsp (5 mL) contains 3 mg sodium.

Store at controlled room temperature 15°-30°C (59°-86°F). You may report side effects by calling 1-888-344-9603 or FDA at 1-800-FDA-1088.

Inactive ingredients

Alcohol, caramel flavor, cherry flavor, citric acid, FD&C Red #40, glycerin, peppermint flavor, purified water, sodium benzoate, sodium saccharin, sorbitol.

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Manufactured by:
Quagen Pharmaceuticals LLC
West Caldwell, NJ 07006

MADE IN USA

PRINCIPAL DISPLAY PANEL-4 fl oz (118 mL) Container Label

Phosphate Oral Solution, USP

100 mg/10 mg per 5 mL

Expectorant/Cough Suppressant

SUGAR FREE, 3.8% (v/v) ALCOHOL

Each 5 mL (1 teaspoonful) contains:
Codeine phosphate, USP..... 10 mg
Guaifenesin, USP ..... 100 mg
(WARNING: May be habit-forming)

MADE IN USA

4 fl oz (118 mL)

Tamper evident by foil seal under ca
if foil seal is broken or mis

NDC 70752-1770

NON VARNISH AI

PEEL HERE

Drug Facts

Active ingredients (in each 5 mL= 1 tsp) — **Purpose**

Codeine phosphate, USP 10 mg ..... Cough suppressant
Guaifenesin, USP 100 mg..... Expectorant

Uses ■ temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
- your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

Ask your doctor before use if
- you have a persistent cough, this may be a sign of a serious condition
- you have a persistent cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- you have a cough that is accompanied by excessive phlegm (mucus)
- you have chronic pulmonary disease or shortness of breath
- giving to a child who is taking other drugs

When using this product
- giving a higher dose than recommended by a doctor could result in serious side effects for your child. A special measuring device should be use to give an accurate dose of this product children under 6 years of age.
- may cause or aggravate constipation

HINGE Minimum 0.5"

HINGE Minimum 0.5"

Drug Facts (continued)

Stop use and ask a doctor if
- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms of a serious condition.

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

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- Do not exceed 6 doses in 24 hours.

Adults and children 12 years of age and over:	2 tsp (10 mL) every 4 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 tsp (5 mL) every 4 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

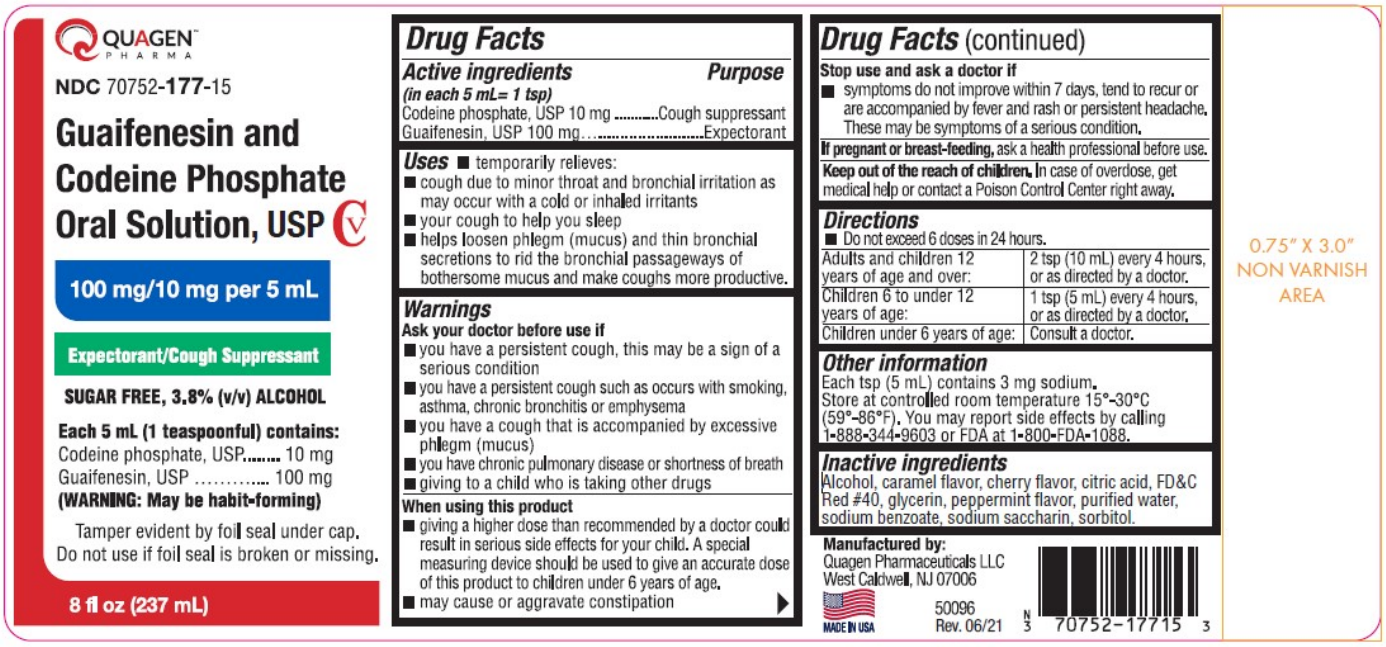
Other information
Each tsp (5 mL) contains 3 mg sodium.
Store at controlled room temperature 15°-30°C (59°-86°F). You may report side effects by calling 1-888-344-9603 or FDA at 1-800-FDA-1088.

Inactive ingredients
Alcohol, caramel flavor, cherry flavor, citric acid, FD&C Red #40, glycerin, peppermint flavor, purified water, sodium benzoate, sodium saccharin, sorbitol.

Manufactured by:
Quagen Pharmaceuticals LLC
West Caldwell, NJ 07006

50094
Rev. 09/21A

PRINCIPAL DISPLAY PANEL-8 fl oz (237 mL) Container Label



QUAGEN PHARMA

NDC 70752-177-15

Guaifenesin and Codeine Phosphate Oral Solution, USP C V

100 mg/10 mg per 5 mL

Expectorant/Cough Suppressant

SUGAR FREE, 3.8% (v/v) ALCOHOL

Each 5 mL (1 teaspoonful) contains:
Codeine phosphate, USP..... 10 mg
Guaifenesin, USP ..... 100 mg
(WARNING: May be habit-forming)

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

8 fl oz (237 mL)

Drug Facts

Active ingredients **Purpose**
(in each 5 mL= 1 tsp)
Codeine phosphate, USP 10 mg .....Cough suppressant
Guaifenesin, USP 100 mg.....Expectorant

Uses ■ temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
- your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings
Ask your doctor before use if
- you have a persistent cough, this may be a sign of a serious condition
- you have a persistent cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- you have a cough that is accompanied by excessive phlegm (mucus)
- you have chronic pulmonary disease or shortness of breath
- giving to a child who is taking other drugs

When using this product
- giving a higher dose than recommended by a doctor could result in serious side effects for your child. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age.
- may cause or aggravate constipation

Drug Facts (continued)

Stop use and ask a doctor if
- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms of a serious condition.

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

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- Do not exceed 6 doses in 24 hours.

Adults and children 12 years of age and over:	2 tsp (10 mL) every 4 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 tsp (5 mL) every 4 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

Other information
Each tsp (5 mL) contains 3 mg sodium.
Store at controlled room temperature 15°-30°C (59°-86°F). You may report side effects by calling 1-888-344-9603 or FDA at 1-800-FDA-1088.

Inactive ingredients
Alcohol, caramel flavor, cherry flavor, citric acid, FD&C Red #40, glycerin, peppermint flavor, purified water, sodium benzoate, sodium saccharin, sorbitol.

Manufactured by:
Quagen Pharmaceuticals LLC
West Caldwell, NJ 07006

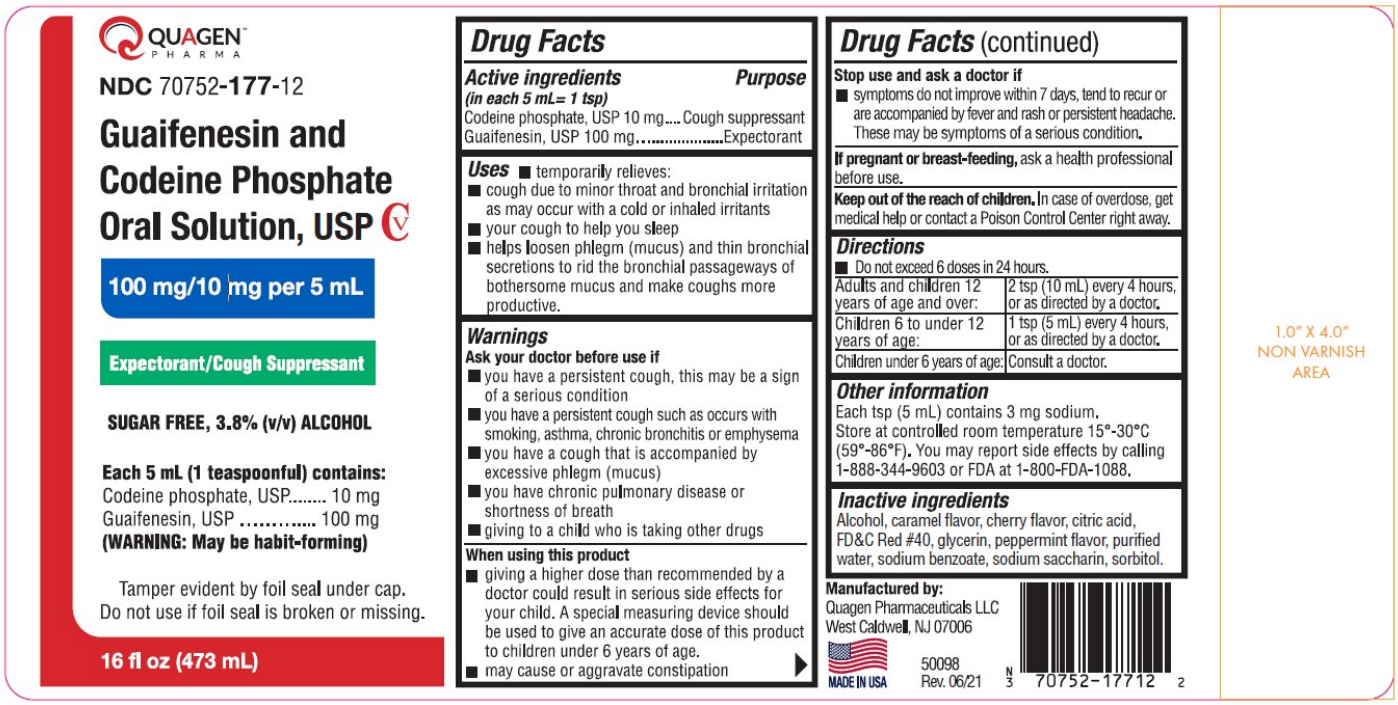
MADE IN USA

50096
Rev. 06/21

N 3 70752-17715 3

0.75" X 3.0"
NON VARNISH
AREA

PRINCIPAL DISPLAY PANEL-16 fl oz (473 mL) Container Label



QUAGEN PHARMA

NDC 70752-177-12

Guaifenesin and Codeine Phosphate Oral Solution, USP C V

100 mg/10 mg per 5 mL

Expectorant/Cough Suppressant

SUGAR FREE, 3.8% (v/v) ALCOHOL

Each 5 mL (1 teaspoonful) contains:
Codeine phosphate, USP..... 10 mg
Guaifenesin, USP ..... 100 mg
(WARNING: May be habit-forming)

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

16 fl oz (473 mL)

Drug Facts

Active ingredients **Purpose**
(in each 5 mL= 1 tsp)
Codeine phosphate, USP 10 mg....Cough suppressant
Guaifenesin, USP 100 mg.....Expectorant

Uses ■ temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
- your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings
Ask your doctor before use if
- you have a persistent cough, this may be a sign of a serious condition
- you have a persistent cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- you have a cough that is accompanied by excessive phlegm (mucus)
- you have chronic pulmonary disease or shortness of breath
- giving to a child who is taking other drugs

When using this product
- giving a higher dose than recommended by a doctor could result in serious side effects for your child. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age.
- may cause or aggravate constipation

Drug Facts (continued)

Stop use and ask a doctor if
- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms of a serious condition.

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

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- Do not exceed 6 doses in 24 hours.

Adults and children 12 years of age and over:	2 tsp (10 mL) every 4 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 tsp (5 mL) every 4 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

Other information
Each tsp (5 mL) contains 3 mg sodium.
Store at controlled room temperature 15°-30°C (59°-86°F). You may report side effects by calling 1-888-344-9603 or FDA at 1-800-FDA-1088.

Inactive ingredients
Alcohol, caramel flavor, cherry flavor, citric acid, FD&C Red #40, glycerin, peppermint flavor, purified water, sodium benzoate, sodium saccharin, sorbitol.

Manufactured by:
Quagen Pharmaceuticals LLC
West Caldwell, NJ 07006

MADE IN USA

50098
Rev. 06/21

N 3 70752-17712 2

1.0" X 4.0"
NON VARNISH
AREA

GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70752-177
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
DEHYDRATED ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CARAMEL, CHERRY, PEPPERMINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70752-177-06	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2022	
2	NDC:70752-177-15	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2022	
3	NDC:70752-177-12	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/23/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/23/2022	

Labeler - QUAGEN PHARMACEUTICALS LLC (073645339)

Registrant - QUAGEN PHARMACEUTICALS LLC (073645339)

Establishment

Name	Address	ID/FEI	Business Operations
QUAGEN PHARMACEUTICALS LLC		080281331	manufacture(70752-177) , pack(70752-177)

Revised: 7/2022 QUAGEN PHARMACEUTICALS LLC