

CHILDRENS MUCUS RELIEF COUGH - CHERRY FLAVOR- dextromethorphan hydrobromide, guaifenesin liquid
AptaPharma Inc.

CHILDREN'S MUCUS RELIEF COUGH - CHERRY FLAVOR

DRUG FACTS

Active ingredients

(in each 5 mL teaspoonful)

Dextromethorphan HBr, USP 5 mg

Guaifenesin, USP 100 mg

Purpose

Dextromethorphan HBr, USP Cough Suppressant

Guaifenesin, USPExpectorant

Uses

- temporarily relieves:cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain the bronchial tube

Warnings

Do not use in a child who is 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 the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

When using this product• do not use more than directed

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache.

These could be signs of a serious condition.

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 6 doses in any 24-hour period

Age

Dose

Children 6 years to

1 to 2 teaspoonfuls (tsps)

Under 12 years	every 4 hours
Children 4 years to	1/2 to 1 teaspoonful (tsp)
Under 6 years	every 4 hours
Children under 4 years	do not use

Other information • each teaspoon contains: sodium 3 mg

- store between 20-25°C (68-77°F) • do not refrigerate
- dosing cup provided • **Keep carton for full direction for use**

Inactive ingredients: anhydrous citric acid, dextrose, D&C red #33, FD&C red #40, flavors, glycerin, maltitol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucralose, xanthan gum

Questions? Call weekdays from 9:30AM to 4:30 PM EST 1-877-798-5944

CHILDREN'S MUCUS RELIEF COUGH CHERRY

AP SAFE

NDC 76281-512-24

**Children's
Cough
Mucus Relief**

**Cough Suppressant
Expectorant**

**Cherry Flavor
4 FL OZ (118 mL)**

DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

*This product is not manufactured or distributed by Reckitt Benckiser Inc., distributor of Children's Mucinex® Cough.

Manufactured by:
AptaPharma Inc.,
1533 Union Ave.
Pennsauken, NJ 08110

Non-Varnish
Glue Area

DO NOT USE IF PRINTED SEAL
UNDER CAP IS TORN OR MISSING

Drug Facts

Active ingredients Purpose
(in each 5 mL teaspoonful)
Dextromethorphan HBr, USP 5 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
■ helps loosen phlegm (mucus) and thin bronchial secretions to drain the bronchial tubes

Warnings
Do not use in a child who is 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 the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
Ask a doctor before use if the child has
■ cough that occurs with too much phlegm (mucus)
■ persistent or chronic cough such as occurs with asthma

When using this product
■ do not use more than directed

Stop use and ask a doctor if
■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

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 6 doses in any 24-hour period

age	dose
Children 6 years to under 12 years	1 to 2 teaspoonfuls (tsp) every 4 hours
Children 4 years to under 6 years	1/2 to 1 teaspoonful (tsp) every 4 hours
Children under 4 years	do not use

Drug Facts (continued)

Other information
■ each teaspoon contains: sodium 3 mg
■ store between 20-25°C (68-77°F)
■ do not refrigerate
■ dosing cup provided
■ Keep carton for full direction for use

Inactive ingredients
anhydrous citric acid, dextrose, D&C red #33, FD&C red #40, flavors, glycerin, maltitol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucralose, xanthan gum

Questions? Call weekdays from 9:30 AM to 4:30 PM EST 1-877-798-9944

*This product is not manufactured or distributed by Reckitt Benckiser Inc., distributor of Children's Mucinex® Cough.

Manufactured by:
AptApharma Inc.,
1533 Union Ave.,
Pennsauken, NJ 08110

AP-BX-13



Non-Varnish
Glue Area



Children's
**Cough
Mucus Relief**
Cough Suppressant
Expectorant

NDC 76281-512-24



COMPARE TO THE ACTIVE
INGREDIENTS IN
CHILDREN'S MUCINEX®
COUGH*

Children's
**Cough
Mucus Relief**

Cough Suppressant
Expectorant

Dextromethorphan HBr 5 mg
Guaifenesin 100 mg

Chest Congestion

- Relieves chest congestion
- Thins & loosens mucus
- For Ages 4 to 12



Cherry Flavor

4 FL OZ (118 mL)

NDC 76281-512-24



COMPARE TO THE ACTIVE
INGREDIENTS IN
CHILDREN'S MUCINEX®
COUGH*

Children's
**Cough
Mucus Relief**

Cough Suppressant
Expectorant

Dextromethorphan HBr 5 mg
Guaifenesin 100 mg

Chest Congestion

- Relieves chest congestion
- Thins & loosens mucus
- For Ages 4 to 12



Cherry Flavor

4 FL OZ (118 mL)

Non-Varnish

NDC 76281-512-24

AP
Aptapharma

**Children's
Cough
Mucus Relief**

**Cough Suppressant
Expectorant**

Dextromethorphan HBr 5 mg
Guaifenesin 100 mg

Chest Congestion

- Relieves chest congestion
- Thins & loosens mucus
- For Ages 4 to 12

4 FL OZ (118 mL) Cherry Flavor

DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

Active ingredients (in each teaspoonful, 5 mL) Purpose
 Dextromethorphan HBr 5 mg.....Cough suppressant
 Guaifenesin 100 mg.....Expectorant

Uses: ■ temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain the bronchial tubes

Warnings: Do not use in a child who is 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 the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough such as occurs with asthma.

When using this product ■ do not use more than directed.
Stop use and ask a doctor if ■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

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 6 doses in any 24-hour period

Age	Dose
Children 6 years to under 12 years	1 to 2 teaspoonfuls (teps) every 4 hours
Children 4 years to under 6 years	1/2 to 1 teaspoonful (tsp) every 4 hours
Children under 4 years	Do not use

Other information: ■ each teaspoon contains: sodium 3 mg
 ■ store between 20-25°C (68-77°F) ■ do not refrigerate
 ■ dosing cup provided ■ **Keep carton for full direction for use**

Inactive ingredients: anhydrous citric acid, dextrose, D&C red #33, FD&C red #40, flavors, glycerin, maltitol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucralose, xanthan gum

Questions? Call weekdays from 9:30 AM to 4:30 PM EST 1-877-798-5844

Manufactured by:
 Aptapharma Inc.,
 1533 Union Ave.
 Pennsauken, NJ 08110 AP-LR-28

LOT:
EXP:

res

CHILDRENS MUCUS RELIEF COUGH - CHERRY FLAVOR

dextromethorphan hydrobromide, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-512
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL 100 mg

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)

GUAIFENESIN

100 mg
in 5 mL**Inactive Ingredients**

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DEXTROSE (UNII: IY9XDZ35W2)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-512-24	1 in 1 CARTON	01/30/2024	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/30/2024	

Labeler - AptaPharma Inc. (790523323)**Registrant** - AptaPharma Inc. (790523323)**Establishment**

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-512)

Revised: 1/2024

AptaPharma Inc.