

**CHILDRENS COLD COUGH AND SORE THROAT MIXED BERRY- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
AptaPharma Inc.**

Children's Cold, Cough & Sore Throat mixed Berry Flavor

Drug Facts

***Active ingredients Purpose
(in each 10 mL)***

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Acetaminophen Pain reliever/fever reducer
Dextromethorphan HBrCough suppressant
Guaifenesin Expectorant
Phenylephrine HClNasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- nasal congestion • stuffy nose • minor aches and pains • sore throat • headache • fever
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tube

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include

- skinreddening • blisters • rash. If skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

Do not use • with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. • 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 your child has

- liver disease • heart disease • high blood pressure • thyroid disease • diabetes • a

breathing problem such as chronic bronchitis • persistent or chronic cough such as occurs with asthma • cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if • your child is taking the blood thinning drug warfarin.

When using this product • do not use more than directed (see Overdose warning)

Stop use and ask a doctor if

- redness or swelling is present
- nervousness, dizziness or sleeplessness occur
- new symptoms occur
- pain, nasal congestion or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- cough comes back, or occurs with rash or headache that lasts.

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.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not use more than directed (see Overdose warning)
- shake well before using
- do not use more than 5 doses in any 24-hour period
- if needed, repeat dose every 4 hours while symptoms last
- do not use more than 5 days unless directed by a doctor
- use dosage cup

Age	Dose
Children 6 to under 12 years of age	10 mL every 4 hours
Children under 6 years of age	Do not use

Other information

- each 10 mL contains: **sodium 5 mg**
- store between 15-30°C (59-86°F)
- do not refrigerate
- dosage cup provided

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, Xanthan gum

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

Maximum Strength MAX COLD & SINUS

AP SAFE

NDC 76281-519-24

Compare to Mucinex[®] FAST-MAX[™] Cold & Sinus
Active ingredients*

Children's

Cold, Cough

& Sore Throat

Pain reliever/Fever Reducer

Cough Suppressant

Expectorant

Nasal decongestant

For Ages 6 to 12

Mixed Berry Flavor

4 FL OZ (118 mL)

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

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

* This product is not manufactured or distributed by Reckitt
Benckiser Inc., distributor of children's Mucinex[®] Cold,
Cough & Sore Throat liquid.

Non-Varnish
Glue Area

DO NOT USE IF PRINTED SEAL UNDER CAP
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Drug Facts

Active Ingredients *Purpose*
(in each 10 mL)
Acetaminophen 325 mg... Pain reliever/fever reducer
Dextromethorphan HBr 10 mg... Cough suppressant
Guaifenesin 200 mg... Expectorant
Phenylephrine HCl 5 mg... Nasal decongestant

Uses
Temporarily relieves these common cold and flu symptoms:
nasal congestion, stuffy nose, minor aches and pains, sore throat, headache, fever
helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes more than 5 doses in 24 hours, which is the maximum daily amount, with other drugs containing acetaminophen.
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash. If skin reaction occurs, stop use and seek medical help right away.
Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.
Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
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 your child has:
liver disease, heart disease, high blood pressure, thyroid disease, diabetes
a breathing problem such as chronic bronchitis, persistent or chronic cough such as occurs with asthma, or cough that occurs with too much phlegm (mucus).
Ask a doctor or pharmacist before use if:
your child is taking the blood thinning drug warfarin.

Drug Facts (continued)

When using this product do not use more than directed (see Overdose warning).
Stop use and ask a doctor if
redness or swelling is present
new rashes occur
new symptoms occur
pain, nasal congestion or cough gets worse or lasts more than 5 days
fever gets worse or lasts more than 3 days
cough comes back, or occurs with rash or headache that lasts.
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Shake well before using.
Do not use more than 5 doses in any 24-hour period.
If needed, repeat dose every 4 hours while symptoms last.
Do not use more than 5 days unless directed by a doctor.
Use dosage cup.

Age	Dose
Children 6 to under 12 years of age	10 mL every 4 hours
Children under 6 years of age	do not use

Other information
Each 10 mL contains: sodium 6 mg
store between 15-30°C (59-86°F)
do not refrigerate. Dosing cup provided.

Inactive ingredients anhydrous citric acid, acetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

Questions? 1-877-798-0944

*This product is not manufactured or distributed by Peckitt Benzocaine Inc., distributor of Children's Mucinex® Cold, Cough & Sore Throat Liquid.
Manufactured by: AptelPharma Inc.,
1533 Union Ave.,
Parsippany, NJ 08116 AP-BK-14

Non-Varnish
Glue Area



Children's Cold, Cough & Sore Throat

Acetaminophen / Guaifenesin /
Dextromethorphan HBr / Phenylephrine HCl

NDC 76281-519-04



COMPARE TO THE
ACTIVE INGREDIENTS IN
CHILDREN'S MUCINEX® COLD,
COUGH & SORE THROAT

Children's Cold, Cough & Sore Throat

Pain Reliever / Fever Reducer
Cough Suppressant
Expectorant
Nasal Decongestant

Acetaminophen / Dextromethorphan HBr /
Guaifenesin / Phenylephrine HCl

Cold & Cough

- Cough & sore throat
- Nasal & chest congestion
- For Ages 6 to 12



Minted Berry Flavor

4 FL OZ (118 mL)



3 76281 51924 2

Non-Varnish

NDC 76281-519-04



COMPARE TO THE
ACTIVE INGREDIENTS IN
CHILDREN'S MUCINEX® COLD,
COUGH & SORE THROAT

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- Cough & sore throat
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Minted Berry Flavor

4 FL OZ (118 mL)

NDC 76281-519-24



Children's Cold, Cough & Sore Throat

Pain Reliever / Fever Reducer
Cough Suppressant, Expectorant,
Nasal Decongestant

Acetaminophen / Dextromethorphan HBr /
Guaifenesin / Phenylephrine HCl

Cold & Cough

- Cough & sore throat
- Nasal & chest congestion
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Uses: Temporarily relieves these common cold and flu symptoms: nasal congestion; stuffy nose; minor aches and pains; sore throat; headache; fever; cough due to minor throat and bronchial irritation; helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes. **Warnings:** Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes more than 5 doses in 24 hours, which is the maximum daily amount, with other drugs containing acetaminophen. Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness; skin rash. If skin reaction occurs, stop use and seek medical help right away. **Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly. **Do not use:** with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist; 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 your child has:** liver disease; heart disease; high blood pressure; thyroid disease; diabetes; a breathing problem such as chronic bronchitis; persistent or chronic cough such as occurs with asthma; cough that occurs with too much phlegm (mucus). **Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.** Stop use and ask a doctor if: redness or swelling is present; nervousness, dizziness or sleeplessness occur; new symptoms occur; pain, nasal congestion or cough gets worse or lasts more than 5 days; fever gets worse or lasts more than 3 days; cough comes back, or occurs with rash or headache that lasts. 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. **Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. **Quick medical attention is critical even if you do not notice any signs or symptoms. Directions:** do not use more than directed (see Overdose warning); shake well before using. Do not use more than 5 doses in any 24-hour period. If needed, repeat dose every 4 hours while symptoms last. Use dose cap. Do not use more than 5 days unless directed by a doctor. Children 6 to under 12 years of age: 10 mL every 4 hours. Children under 6 years of age: Do not use. **Other information:** Each 10 mL contains: sodium 5 mg. Store between 15-30°C (59-86°F). Do not refrigerate. **Keep carton for full labeling. Inactive ingredients:** anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum. **Questions?** 1-877-798-5944

LOT: _____
EXP: _____

Manufactured by:
AptaPharma Inc.,
1533 Union Ave.,
Pennsauken, NJ 08110 AP-LR-29

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CHILDRENS COLD COUGH AND SORE THROAT MIXED BERRY			
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-519
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL	
Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYL GALLATE (UNII: 8D45NN7V92)			
WATER (UNII: 059QF0KO0R)			

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-519-24	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(76281-519)

Revised: 2/2024

Aptapharma Inc.