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

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#### 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**

#### 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

- $\bullet$  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	10 mL every 4
of age	hours
Children under 6 years of age	Do not use

#### Other information

- each 10 mL contains: sodium 5 mg
- store between IS-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<sup>®</sup> FAST-MAX<sup>™</sup> Cold & Sinus Active ingredients\*

Children's

Cold, Cough

& Sore Throat

Pain reliever/Fever Reducer Cough Suppresant 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

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Purpose

Drug Facts

Active ingredients

Children's

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#### Cold, Cough & Sore Throat

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MDC 78281-519-04

COMPARE TO THE ACTIVE INCREDIENTS IN CHILDREN'S MUCHIEUS COLD, COUGH & SORE THREAT

# Children's

- · Cough & sore throat
- · For Ages 6 to 12



## Cold, Cough & Sore Throat

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

Acetaminophen / Dextromethorphan HBr / Guailenesin / Phenylephrine HCI

#### Cold & Cough

- Nasal & chest congestion



4 FL OZ (118 mL)

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Manufactured by: AptaPharma Inc.,

Questions? 1-877-798-5944

Drug Facts (continued)

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Non-Varnish Glue Area

Non-Varnish



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#### CHILDRENS COLD COUGH AND SORE THROAT MIXED BERRY

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-519
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 10 mL		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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: 8D4SNN7V92)				
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			

P	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.