

COUGH COLD AND SORE THROAT CHILDRENS- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid Walgreens

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.

Drug Facts

Active ingredients (in each 10 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - cough due to minor throat and bronchial irritation
 - the intensity of coughing
 - the impulse to cough to help your child get to sleep
 - nasal congestion
 - stuffy nose
 - sore throat
 - minor aches and pains
 - headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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 reddening
- blisters
- rash

If a 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.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if your child has

- liver disease
- heart disease
- high blood pressure
- diabetes
- thyroid disease
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma

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

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

These could be signs of a serious condition.

Keep out of reach of children

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 (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see Overdose warning)**
- do not give more than 5 doses in any 24-hour period
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 days unless directed by a doctor
- keep dosing cup with product
- use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- dose as follows, or as directed by a doctor
- mL=milliliter
- **children 6 to under 12 years of age:** 10 mL in dosing cup provided
- **children under 6 years of age:** do not use

Other information

- **each 10 mL contains:** sodium 6 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, EDTA disodium, FD&C blue #1, FD&C red #40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol, sucralose, xanthan gum

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredients in Children's Mucinex® Cold, Cough & Sore Throat††

Children's

Cold, Cough & Sore Throat

ACETAMINOPHEN 325 mg /

PAIN RELIEVER / FEVER REDUCER

DEXTROMETHORPHAN HBr 10 mg /

COUGH SUPPRESSANT

GUAIFENESIN 200 mg / EXPECTORANT

PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT

- Relief from cough, sore throat, stuffy nose & chest congestion
- Breaks up mucus

AGES 6 - 11 YEARS

FL OZ (mL)

Berry flavor

††This product is not manufactured or distributed by Reckitt Benckiser, distributor of Children's Mucinex® Cold, Cough & Sore Throat.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com

Package Label

Drug Facts (continued)

Stop use and ask a doctor if

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

Keep out of reach of children.

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 (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed (see Overdose warning)
- do not give more than 5 doses in any 24-hour period
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 days unless directed by a doctor
- use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- keep dosing cup with product
- dose as follows, or as directed by a doctor
- children 6 to under 12 years of age: 10 mL in dosing cup provided
- children under 6 years of age: do not use

Other information

- each 10 mL contains: sodium 6 mg
- store between 20°-25°C (68°-77°F). Do not refrigerate.

Inactive ingredients citric acid, disodium EDTA, FD&C blue #1, FD&C red #40, flavors, glycerin, propyl galate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or comments?
Call 1-877-753-3836 Monday-Friday 9AM-5PM EST

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING

PARENTS:
Learn about form medication abuse
www.StopMedicineAbuse.org

*Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.
††This product is not manufactured or distributed by Reckitt Benckiser, distributor of Children's Mucinex® Cold, Cough & Sore Throat.

NDC 0363-4050-04



Compare to the active ingredients in Children's Mucinex® Cold, Cough & Sore Throat*

Children's Cold, Cough & Sore Throat

ACETAMINOPHEN 325 mg / PAIN RELIEVER / FEVER REDUCER
DEXTROMETHORPHAN HBr 10 mg / COUGH SUPPRESSANT
GUAIFENESIN 200 mg / EXPECTORANT
PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT

- Relief from cough, sore throat, stuffy nose & chest congestion
- Breaks up mucus



AGES 6-11 YEARS

4 FL OZ (118 mL) Berry flavor

NDC 0363-4050-04



Compare to the active ingredients in Children's Mucinex® Cold, Cough & Sore Throat*

Children's Cold, Cough & Sore Throat

ACETAMINOPHEN 325 mg / PAIN RELIEVER / FEVER REDUCER
DEXTROMETHORPHAN HBr 10 mg / COUGH SUPPRESSANT
GUAIFENESIN 200 mg / EXPECTORANT
PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT

- Relief from cough, sore throat, stuffy nose & chest congestion
- Breaks up mucus



AGES 6-11 YEARS

4 FL OZ (118 mL) Berry flavor

Drug Facts

Active Ingredients (in each 10 mL) Purposes

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
- cough due to minor throat and bronchial irritation
- the intensity of coughing
- the impulse to cough to help your child get to sleep
- nasal congestion
- stuffy nose
- sore throat
- minor aches and pains
- headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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 reddening, blisters, rash. If a 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.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if your child has

- liver disease
- heart disease
- high blood pressure
- diabetes
- thyroid disease
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma

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).

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
walgreens.com ©2021 Walgreen Co.

ITEM 357419 W10024-0322-L



PLD-E350C F0008008 W3ORG0222-F

Lot No:
Exp. Date:

WALGREENS Children's Cold, Cough, and Sore Throat Berry Flavor

COUGH COLD AND SORE THROAT CHILDRENS

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-4050
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: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

GUAIFENESIN (UNII: 493W7431VQ) (GUAIFENESIN - UNII:493W7431VQ)	GUAIFENESIN	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)	
PROPYL GALLATE (UNII: 8D45NN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KOOR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4050-04	1 in 1 BOX	10/31/2014	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/31/2014	

Labeler - Walgreens (008965063)