DRKIDS CHILDREN MULTI SYMPTOM COLD AND FLU- acetaminophen 320mg, chlorpheniramine maleate 2mg, dextromethorphan hbr 10mg, phenylephrine hcl 5mg solution Calmco

DrKids Children's Multi-Symptoms Cold & Flu

Active Ingredient (in each 10mL)

Acetaminophen, 320mg
Chlorpheniramine Maleate, 2mg
Dextromethorphan HBr, 10mg t
Phenylephrine HCl, 5mg

Purpose

Pain reliever / fever reducer
Antihistamine
Cough suppressant
Nasal decongestant

Uses

- \blacksquare temporarily relieves the following cold/flu symptoms: \blacksquare minor aches and pains \blacksquare headache \blacksquare sore throat \blacksquare cough \blacksquare stuffy nose
- sneezing and runny nose temporarily reduces fever

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 for this product
- 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
- to make a child sleepy
- 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 has is allergic to any of the ingredients in this product

Ask a doctor befre use if your child has

■ liver disease ■ high blood pressure ■ heart disease ■ diabetes ■ thyroid disease ■ glaucoma ■ 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 cotor or pharmacist before use if your child is

■ taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers

When using this product

- do not exceed recommended dosage (see overdose warning)
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase the drowsiness effect

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 ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ cough comes back or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

Keep out of reach of children

Overdose section

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

- **■** this product does not contain directions or complete warning for adult use
- **■** do not give more than directed (see overdose warning)
- find right dosage on chart below
- empty each Single-Use Vial of all liquid when dosing, following the instructions under

"Easy to use" on the side panel

- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- children under the age of 6, do not use

Dosing Chart

Age (Years) Dose (mL)

6 - 11 years 1 Single use vial (10mL) every 4 hours. Do not give more than 5 times in 24 hours

Inactive ingredients

citric acid, edetate disodium, glycerin, maltitol, mixed berry flavor, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sorbitol, sucralose, trisodium citrate, xanthan gum.

Other information

- each Single -Use vial contains 11mg of sodium
- store at 20-25°C (68-77°F)
- tamper-evident: do not use if the top flap of the box is open. Do not use if any vial is open or broken.

Questions or comments

Call 941-202-3207 or visit www.drkids.com

Package



DRKIDS CHILDREN MULTI SYMPTOM COLD AND FLU

acetaminophen 320mg, chlorpheniramine maleate 2mg, dextromethorphan hbr 10mg, phenylephrine hcl 5mg solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73282-0113
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	320 mg in 10 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE	5 mg in 10 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	2 mg in 10 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
MALTITOL (UNII: D65DG142WK)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
SORBITOL SOLUTION (UNII: 8KW3E207O2)			
SODIUM METABISULFITE (UNII: 4VON5FNS3C)			

WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BERRY (MIXED BERRY FLAVOR)	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73282- 0113-6	16 in 1 CARTON	02/15/2024	
1		10 mL in 1 VIAL; 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	02/15/2024	

Labeler - Calmco (079308308)

Revised: 12/2023 Calmco