HEALTHY ACCENTS MULTI SYMPTOM COLD- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl suspension DZA Brands LLC

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.

DZA Brands, LLC Multi-Symptom Cold Drug Facts

Active ingredients (in each 5 mL = 1 teas poon)

Acetaminophen 160 mg
Chlorpheniramine maleate 1 mg
Dextromethorphan HBr 5 mg
Phenylephrine HCl 2.5 mg

Purpose

Pain reliever/fever reducer Antihistamine Cough suppressant Nasal decongestant

Uses

- temporarily relieves the following cold/flu symptoms:
- minor aches and pains
- headache
- sore throat
- cough
- 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
- with other drugs containing acetaminophen

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 ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if the child has

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

Ask a doctor or pharmacist before use if the child is

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

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- may cause marked drowsiness
- sedatives and tranquilizers may increase drowsiness

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 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. (1-800-222-1222) 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 Liver warning)
- shake well before using
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- if needed, repeat dose every 4-6 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

Weight (lb)	Age (yr)	Dose (tsp or mL)
under 36 lbs	under 4 years	do not use
36-47 lbs	4-5 years do not use unless directed by a do	
48-95 lbs	6-11 years	2 tsp or 10 mL

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Other information

- each teaspoon contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing

Inactive ingredients

anhydrous citric acid, calcium sulfate, carrageenan, D&C red #33, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, tribasic sodium phosphate, xanthan gum

Questions or comments?

1-866-322-2439

Principal Display Panel

children's

pain relief plus

multi-symptom cold

Fever Reducer - Pain Reliever - Antihistamine

Cough Suppressant - Nasal Decongestant

fever & sore throat (acetaminophen)

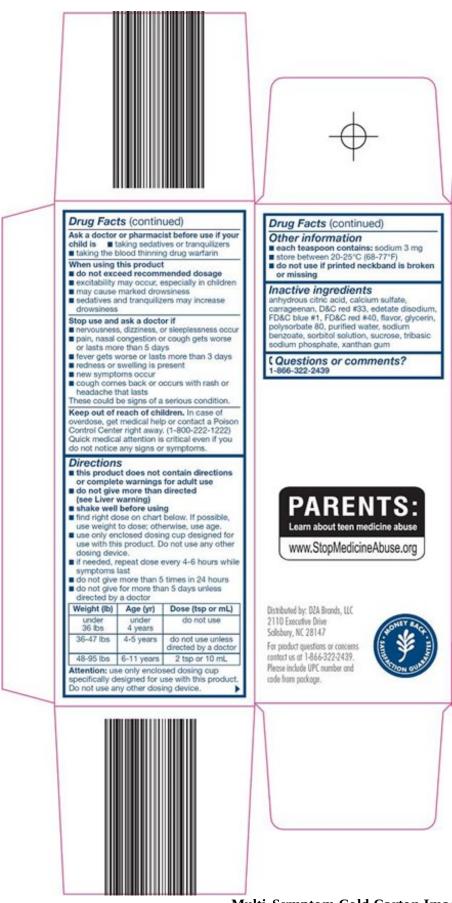
cough (dextromethorphan HBr)

stuffy nose (phenylephrine HCl)

sneezing & runny nose (chlorpheniramine maleate)

Compare to Children's Tylenol® Plus Multi-Symptom Cold active ingredients





Multi-Symptom Cold Carton Image 1

HEALTHY ACCENTS MULTI SYMPTOM COLD

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-903
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362091TL9D) (ACETAMINOPHEN - UNII:362091TL9D)	ACETAMINOPHEN	160 mg in 5 mL	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CARRAGEENAN (UNII: 5C69 YCD2YJ)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCROSE (UNII: C151H8M554)		
XANTHAN GUM (UNII: TTV12P4NEE)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
CALCIUM SULFATE (UNII: WAT0 DDB 50 5)		
SODIUM PHO SPHATE, TRIBASIC (UNII: A752Q30 A6 X)		

Product Characteristics			
Color	PURPLE (opaque)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

OTC monograph final	part341	06/06/2011	
Marketing Categor	, II	Marketing Start Date	Marketing End Date
Marketing Information			
1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
1 NDC:55316-903-26	1 in 1 CARTON	06/06/2011	

Labeler - DZA Brands LLC (090322194)

Revised: 12/2018 DZA Brands LLC