CHILDRENS PLUS COUGH AND RUNNY NOSE- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide suspension Best Choice (Valu Merchandisers Company)

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 5 mL)

Acetaminophen 160 mg

Chlorpheniramine maleate 1 mg

Dextromethorphan HBr 5 mg

Purposes

Pain reliever/fever reducer

Antihistamine

Cough suppressant

Uses

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

Warnings

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

- more than 5 doses (10 mL each) in 24 hours, which is the maximum daily amount
- with other drugs contaning 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

- 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.

- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if the child has

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

Ask a doctor or pharmacist before use if the child is taking

- sedatives or tranquilizers
- the blood thinning drug warfarin

When using this product

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

Stop use and ask a doctor if

- new symptoms occur
- fever gets worse or lasts for more than 3 days
- redness or swelling is present
- pain or cough gets worse or lasts for more than 5 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.

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.
- mL = milliliter
- shake well before using
- do not give more than 5 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- if needed, repeat dose every 4 hours while symptoms last
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age

Weight (lb)	Age (yr)	Dose (mL)
48-95	6-11	10 mL
DE 47	1 E	do not use unless directed by a

JO-4/	4-5	doctor
under 36	under 4	do not use

Other Information

• store between 20-25°C (68-77°F). Do not refrigerate

Inactive ingredients

acesulfame potassium, alcohol, carboxymethylcellulose sodium, citric acid, D&C red #33, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments?

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

Principal Display Panel

Children's Plus Cough & Runny Nose

Acetaminophen / Pain Reliever / Fever Reducer

Chlorpheniramine maleate / Antihistamine

Dextromethorphan HBr / Cough Suppressant

Cherry Flavor

Alcohol 0.02%

Oral suspension

FL OZ (mL)

Dosage Cup Provided

Compare to Children's Tylenol® Plus Cough & Runny Nose active ingredients*

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Plus Cough & Runny Nose.

PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO

5000 KANSAS AVE

KANSAS CITY, KS 66106

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

Package Label

Drug Facts (continued)

Geep 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 for adults as well as children even if you do not notice any signs or symptoms.

Directions

this product does not contain directions or co

- warnings for adult use
 mL = milliter shake well before using
- find the right dose on chart below. If possible, use weight to dose:

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

Other information

store between 20-25°C (68-77°F). Do not refrigerate

Inactive ingredients acesultame potassium, alcoho lose sodium, citric acid, D&C red #33, FD&C red #40, flavors, glycerin, high fructose com syrup, microcrystalline cellulose, purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

*This product is not manufactured or distributed by McNeil Consumer re, distributor of Children's Tylenol® Plus Cough & Runny Nose





PROUDLY DISTRIBUTED BY: VALU MERCHANDISERS, CO. 5000 KANSAS AVE KANSAS CITY, KS 66106

For Ages 6 to 11 Years

COMPARE TO THE

ACTIVE INGREDIENTS IN

COUGH & RUNNY NOSE*

CHILDREN'S TYLENOL® PLUS

Children's

PLUS COUGH &



For Ages 6 to 11 Years



COMPARE TO THE **ACTIVE INGREDIENTS IN** CHILDREN'S TYLENOL® PLUS COUGH & RUNNY NOSE*

Children's **PLUS COUGH & RUNNY NOSE**



Acetaminophen

· Pain Reliever / Fever Reducer **Chlorpheniramine Maleate**

Antihistamine

Dextromethorphan HBr

· Cough Suppressant

CHERRY FLAVOR

Alcohol 0.02% **Oral Suspension** 4 FL 0Z (118 mL)

Acetaminophen

· Pain Reliever / Fever Reducer

Chlorpheniramine Maleate

Antihistamine

Dextromethorphan HBr

Cough Suppressant

CHERRY FLAVOR

Alcohol 0.02% Oral Suspension 4 FL 0Z (118 mL)

Drug Facts

Active ingredients (in each 5 mL) Purposes Chlorpheniramine maleate 1 mg. Dextromethorphan HBr 5 mg.....

..Cough suppressant Uses ■ temporarily relieves the following cold/flu symptoms ■ minor aches and pains ■ sore throat ■ cough ■ sneezing and runny nose ■ headache

norarily reduces fever

Warnings Liver warning: This product contains acetaminophen. Severe liver

damage may occur if your child takes:

more than 5 doses (10 mL each) in 24 hours, which is the

■ more man ouese (iv in each) in 24 nours, which is the maximum daily amount ■ with other drugs containing acetaminophen Allergy after Avotaminophen may cause severe skin reactions. Symptoms may induct. ■ skin redening ■ bisters ■ 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 ■ to make a child sleepy
■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains

narptess poor, in you are the sale without a congression and a contain a contain a contain and the contain a conditions, or Parkinson's disease), or for 2 weeks after stopping 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

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 Iver disease

glaucoma was breathing problem such as chronic bronchitis
cough that occurs with too much philegm (mucus)
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
■ sedatives or tranquilizers

When using this product ■ do not exceed recommended dose (see Overdose warning)

excitability may occur, especially in children
 marked drowsiness may occur
 sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- new symptoms occur
 redness or swelling is present ■ pain or cough gets worse or lasts more than 5 days
- er gets worse or lasts more than 3 days ugh comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.



Best Choice Children's Plus Cough & Runny Nose Cherry Liquid

CHILDRENS PLUS COUGH AND RUNNY NOSE

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide suspension

Product Information

HUMAN OTC DRUG Product Type Item Code (Source) NDC:63941-297

ORAL Route of Administration

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength 160 mg ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D) **ACETAMINOPHEN** in 5 mL CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE -**CHLORPHENIRAMINE** 1 mg UNII:3U6IO1965U) MALEATE in 5 mLDEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) **DEXTROMETHORPHAN** 5 mg

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)		
WATER (UNII: 059QF0KO0R)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
XANTHAN GUM (UNII: TTV12P4NEE)		
ALCOHOL (UNII: 3K9958V90M)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:63941-297- 04	1 in 1 BOX	08/31/2015	
1	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category Application Number or Monograph Citat		Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	08/31/2015		

Labeler - Best Choice (Valu Merchandisers Company) (868703513)

Revised: 7/2016