EQUATE CHILDRENS MULTI SYMPTOM COLD NIGHTTIME - acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid
Wal-Mart Stores, Inc.

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.

Equate Children's Multi-Symptom Cold Nighttime

ACTIVE INGREDIENTS (in each 10 mL)

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenyephrine HCl 5 mg

PURPOSE

Pain reliever / fever reducer

Antihistamine/Cough Suppressant

Nasal decongestant

USE(S)

temporarily relieves these common cold and flu symptoms:

- cough
- sore throat
- nasal congestion
- runny nose
- minor aches and pains
- headache
- sinus congestion and pressure
- sneezing
- temporarily reduces fever
- controls cough to help your child get to sleep

WARNINGS

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

- more than 5 doses in 24 hous, 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.
- to make a child sleepy
- with any other product containing diphenhydramine, even one used on the skin.
- 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 THE CHILD HAS

- liver disease
- thyroid disease
- diabetes
- heart disease
- high blood pressure
- 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 DOCTOR OR PHARMACIST BEFORE USE IF YOUR CHILD

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

WHEN USING THIS PRODUCT

- do not use more than directed (**see Overdose warning**)
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase dowsiness

STOP USE AND ASK 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

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 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)**
- **shake well before use**
- 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
- measure only with dosing cup provided
- do not use dosing cup with other products
- 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 10 mg
- store between 15-30°C (59-86°F)
- do not refrigerate
- dosing cup provided

INACTIVE INGREDIENTS

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

QUESTIONS OR COMMENTS

1-888-287-1915

PRINCIPAL DISPLAY PANEL

NDC 49035-623-03

equate

Compare to Children's Mucinex® Nighttime Multi-Symptom Cold active ingredients*

Children's

MULTI-SYMPTOMS COLD
NIGHTTIME

Acetaminophen 325 mg
Pain reliever/Fever Reducer

Diphenhydramine HCl 12.5 mg

Antihistamine/Cough Suppressant

Phenylephrine HCl 5 mg

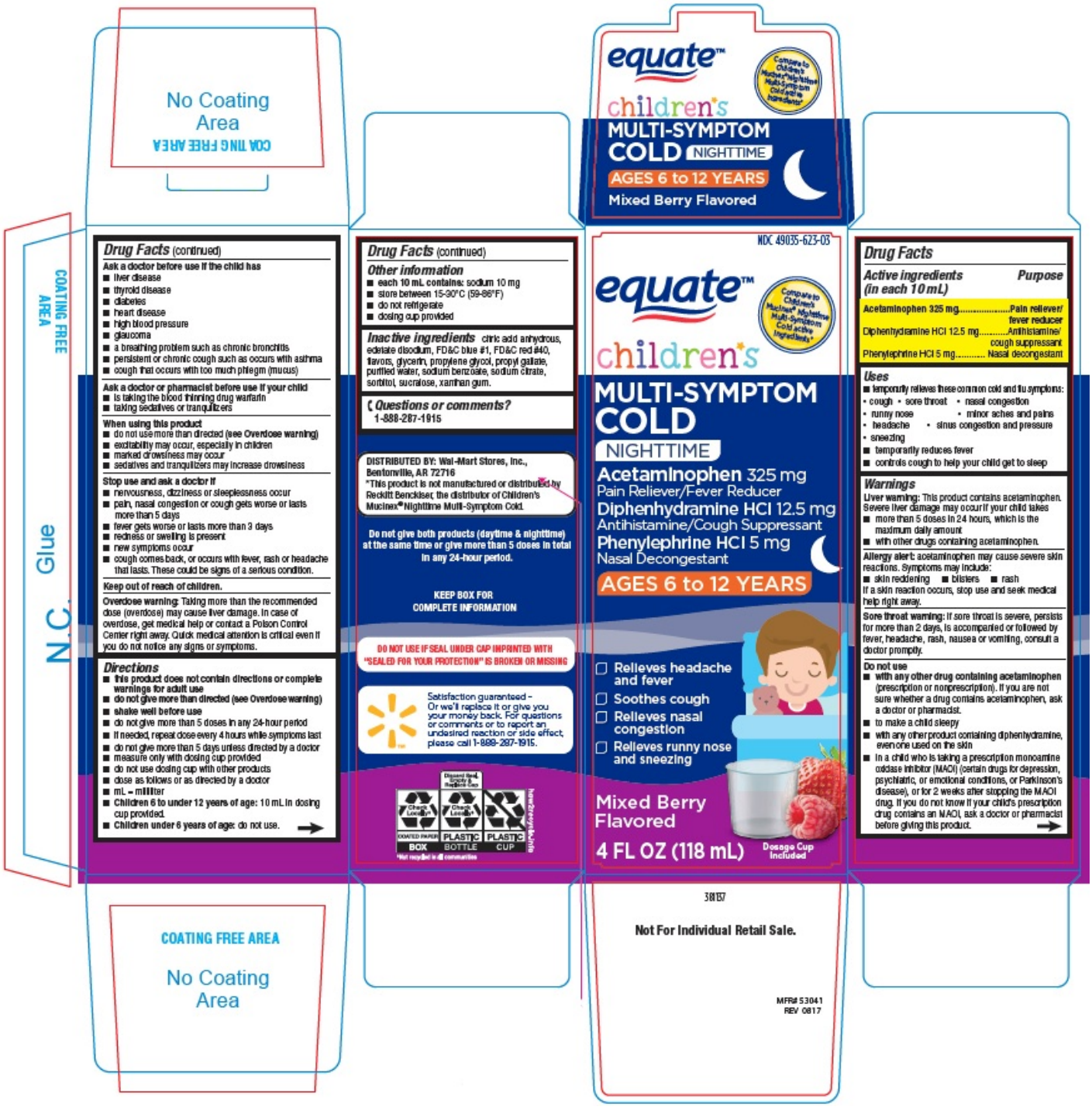
Nasal Decongestant

AGES 6 to 12 YEARS

- Relieves headache and fever
- Soothes cough
- Relieves nasal congestion
- Relieves runny nose and sneezing

Mixed Berry Flavored

4 FL OZ (118 mL)



EQUATE CHILDRENS MULTI SYMPTOM COLD NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49035-623
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
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 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)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	BLUE	**Score**	
Shape		**Size**	
Flavor	BERRY (Mixed Berry)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-623-03	1 in 1 CARTON	08/01/2017	
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 FINAL	part341	08/01/2017	

Labeler - Wal-Mart Stores, Inc. (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(49035-623)

Revised: 11/2022 Wal-Mart Stores, Inc.