EQUATE NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution WALMART 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.

Wal-Mart Nighttime Cold & Flu Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine Succinate 6.25 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- minor aches and pains
- headache
- fever
- sore throat
- runny nose and sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

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.
- if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- to make a child sleepy
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- glaucoma
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

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

When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

| adults & children 12 yrs & over | 30 mL every 4 hrs |
|---------------------------------|-------------------|
| children 6 to under 12 yrs | 15 mL every 4 hrs |
| children 4 to under 6 yrs | ask a doctor |
| children under 4 yrs | do not use |

Other information

- each 15 mL contains: sodium 15 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C green #3, FD&C red #40, FD&C yellow #6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions?

1-888-287-1915

Package/Label Principal Display Panel

equate™

Compare to Vicks® NyQuil® Severe Honey Flavor active ingredients

NIGHTTIME SEVERE HONEY FLAVOR

Cold & Flu

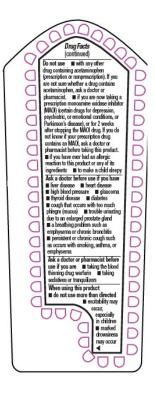
Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine, Nasal Decongestant Nighttime Relief

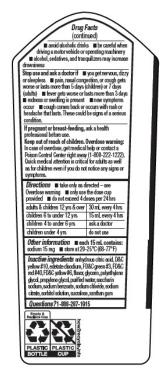
- Acetaminophen Minor aches & pains, fever
- Phenylephrine HCl Nasal congestion & sinus pressure
- Dextromethorphan HBr Cough
- Doxylamine Succinate Runny nose & sneezing

12 FL OZ (355mL)









EQUATE NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79903-122 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|--|----------------------------------|---------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) | ACETAMINOPHEN | 325 mg in 15 mL | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 15 mL | |
| DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg in 15 mL | |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg in 15 mL | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | |

| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
|---|--|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:79903-122- 12 | 1 in 1 CARTON | 06/30/2023 | |
| 1 | | 355 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 | 06/30/2023 | |
| | | | |

Labeler - WALMART INC. (051957769)

Revised: 10/2023 WALMART INC.