COLD AND FLU PLUS CONGESTION NIGHTTIME- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl solution WALMART INC.

Equate 44-060

Active ingredients (in each 30 mL)

Acetaminophen 650 mg Dextromethorphan HBr 20 mg Doxylamine succinate 12.5 mg Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer Cough suppressant Antihistamine Nasal decongestant

Uses

- temporarily relieves common cold and flu symptoms:
 - runny nose and sneezing
 - nasal congestion
 - sore throat
 - headache
 - minor aches and pains
 - cough to help you sleep
 - sinus congestion and pressure
 - cough due to minor throat and bronchial irritation
- temporarily reduces fever
- 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 if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- glaucoma
- heart disease
- high blood pressure
- liver disease
- thyroid disease
- diabetes

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 exceed recommended dosage.

- do not exceed recommended dosage
- excitability may occur, especially in children
- avoid alcoholic beverages
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 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.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed
- mL = milliliter
- only use the dose cup provided
- do not exceed 4 doses per 24 hours
- adults and children 12 years and over: 30 mL every 4 hours
- children under 12 years: do not use

Other information

- each 30 mL contains: sodium 11 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

anhydrous citric acid, D&C yellow #10, FD&C blue #1, flavors, glycerin, polyethylene glycol 400, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sodium saccharin, sorbitol, sucralose

Questions or comments?

1-888-287-1915

equate™

Principal display panel

NDC 79903-191-12

Compare to Vicks® NYQuil® VapoCOOL® Severe Cold & Flu + Congestion active ingredients*

NIGHTTIME SEVERE

VAPOR CHILLING

COLD & FLU + CONGESTION

ACETAMINOPHEN-Pain Reliever/ Fever Reducer Dextromethorphan HBr-Cough Suppressant Doxylamine Succinate- Antihistamine Phenylephrine HCI-Nasal Decongestant

Relieves:

- Headache, fever, sore throat, minor aches & pains
- Nasal congestion, sinus pressure
- Sneezing, runny nose
- Cough

For Ages 12+

12 FL OZ (355 mL)

F-060 ORG

TAMPER EVIDENT: DO NOT USE IF PRINTED NECK WRAP IS BROKEN OR MISSING

DISTRUBUTED BY: Walmart Inc., Bentoville, AR 72716 *This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks® NyQuil® VapoCOOL® SEVERE COLD & FLU + CONGESTION.

50844 ORG062306002





Equate 44-060

COLD AND FLU PLUS CONGESTION NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl solution

| Product | Informatio | on | | | | | | | |
|---|------------------------------|--------------------|-----------------------------------|-----------|--------------|-------------------------|------|---------------------|--|
| Product Type | | | HUMAN OTC DRUG | | | Code (Source) | | NDC:79903-191 | |
| | Route of Administration ORAL | | | | . , | | | | |
| Noute of F | , anning crach | 011 | | | | | | | |
| | | | | | | | | | |
| Active In | gredient/A | ctive | Moiety | | | | | | |
| | | Ingred | lient Name | | | Basis of Stre | ngth | Strength | |
| ACETAMINO | | 650 mg in 30 mL | | | | | | | |
| DEXTROME (DEXTROMET | AN | 20 mg in 30 mL | | | | | | | |
| (DEXTROMETHORPHAN - UNII:7355X3ROTS)HYDROBROMIDEDOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)DOXYLAMINE SUCCINATE | | | | | | | | 12.5 mg in 30 mL | |
| | | CHLORI | DE (UNII: 04JA59TNSJ) (PHE | NYLEPHRII | NE - | PHENYLEPHRINE | | 10 mg | |
| UNII:1WS297 | W6MV) | | | | | HYDROCHLORIDE | | in 30 mL | |
| | | | | | | | | | |
| Inactive | Ingredient | S | | | | | | | |
| | | | Ingredient Name | | | | 9 | Strength | |
| ANHYDROU | S CITRIC ACI |) (UNII:) | • | | | | | 5 | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | | | | | | | | |
| FD&C BLUE | NO. 1 (UNII: H | H3R47K3 | TBD) | | | | | | |
| GLYCERIN (| UNII: PDC6A3C | 0OX) | | | | | | | |
| POLYETHYL | ENE GLYCOL | 400 (UI | NII: B697894SGQ) | | | | | | |
| PROPYLENE | GLYCOL (UN | II: 6DC9 | Q167V3) | | | | | | |
| WATER (UN | I: 059QF0KO0F | R) | | | | | | | |
| | NZOATE (UNII | - | | | | | | | |
| | ILORIDE (UNII: | | | | | | | | |
| | | | E (UNII: B22547B95K) | | | | | | |
| | SODIUM (UNI | | UX40TY) | | | | | | |
| | UNII: 506T60A | - | | | | | | | |
| SUCKALUSI | (UNII: 96K6UC | 23ZD4) | | | | | | | |
| | | | | | | | | | |
| Product | Characteri | stics | | | | | | | |
| Color | | green | green (bluish) | | | re | | | |
| Shape | | | | | Size | • | | | |
| Flavor | | MINT (eucalyptus) | | | Imprint Code | | | | |
| Contains | | | | | | | | | |
| | | | | | | | | | |
| Packaging | | | | | | | | | |
| # Item C | ode | Pa | ackage Description | | Μ | larketing Start Date | Mar | keting End Date | |
| 1 NDC:79903- 191-12 355 mL in 1 BOTTLE, PLASTIC; Type 0: No Combination Product | | | | a | 08 | /16/2023 | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-------------------------|---------------------------------|-----------------|---------------|
| Category | Citation | Date | Date |
| OTC Monograph Drug M012 | | 08/16/2023 | |

Labeler - WALMART INC. (051957769)

| Establishment | | | | | | | | |
|-------------------------|---------|-----------|--|--|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | | |
| LNK International, Inc. | | 967626305 | manufacture(79903-191) , pack(79903-191) | | | | | |

Revised: 8/2023

WALMART INC.