

BASIC CARE NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride tablet, film coated
Amazon.com Services 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.

Amazon Nighttime Severe Cold & Flu Drug Facts

Active ingredients (in each caplet)

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 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

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- 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
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

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

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 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.

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
- do not exceed 8 caplets per 24 hrs

| | |
|---------------------------------|----------------------------------|
| adults & children 12 yrs & over | 2 caplets with water every 4 hrs |
| children 4 to under 12 yrs | ask a doctor |
| children under 4 yrs | do not use |

Inactive ingredients

crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Nighttime Relief

Compare to Vicks® NyQuil® Severe+ VapoCOOL™

active ingredients

Nighttime Severe Cold & Flu

Acetaminophen, Phenylephrine HCl, Doxylamine Succinate, Dextromethorphan HBr

actual size

Pain Reliever/Fever Reducer, Nasal Decongestant, Antihistamine, Cough Suppressant
 Max Strength
 Vapor Ice™
 24 CAPLETS

| | | | | | | | |
|--|----------------------------------|----------------------------------|----------------------------|--------------|----------------------|------------|--|
| <p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> take only as directed – see overdose warning do not exceed 8 caplets per 24 hrs <table border="1"> <tr> <td>adults & children 12 yrs & over</td> <td>2 caplets with water every 4 hrs</td> </tr> <tr> <td>children 4 to under 12 yrs</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 yrs</td> <td>do not use</td> </tr> </table> | adults & children 12 yrs & over | 2 caplets with water every 4 hrs | children 4 to under 12 yrs | ask a doctor | children under 4 yrs | do not use | <p>Drug Facts (continued)</p> <p>Inactive ingredients crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, silicon dioxide, stearic acid, sucrose, talc, titanium dioxide</p> <p>Questions or comments? 1-800-719-9260</p> |
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72/62 BN-C1

Nighttime Relief

NDC 72288-721-62

Compare to
 Vicks® NyQuil®
 Severe+
 VapoCOOL™
 active ingredients*

Nighttime Severe Cold & Flu

Acetaminophen, Phenylephrine HCl,
 Doxylamine Succinate,
 Dextromethorphan HBr

Pain Reliever/Fever Reducer, Nasal Decongestant,
 Antihistamine, Cough Suppressant

Max Strength

24 CAPLETS

actual size



Vapor Ice™

8 42379 19072 8

GLUTEN FREE

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil® Severe+ VapoCOOL™. Store at 20-25°C (68-77°F).

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

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 AMAZON.COM SERVICES LLC
 410 TERRY AVENUE N.
 SEATTLE, WA 98109

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Multi-Symptom Relief

- Minor Aches & Pains, Fever
- Nasal Congestion & Sinus Pressure
- Sneezing, Runny Nose
- Cough

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Drug Facts

Active ingredients (in each caplet)

Purpose

| | |
|-----------------------------------|-----------------------------|
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| Dextromethorphan HBr 10 mg..... | Cough suppressant |
| Doxylamine succinate 6.25 mg..... | Antihistamine |
| Phenylephrine HCl 5 mg..... | 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

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Ask a doctor before use if you have ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ glaucoma ■ 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 ■ trouble urinating due to an enlarged prostate gland

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acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72288-721 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | GREEN | Score | no score |
| Shape | OVAL | Size | 19mm |
| Flavor | | Imprint Code | L72V |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:72288-721-62 | 12 in 1 CARTON | 12/10/2020 | |

| | | | |
|---|--|--|--|
| 1 | 2 in 1 BLISTER PACK; 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 | 12/10/2020 | |

Labeler - Amazon.com Services LLC (128990418)

Revised: 12/2020

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