COLD AND FLU SEVERE NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride capsule, liquid filled
TOPCO ASSOCIATES 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.

Cold and Flu Severe Nighttime

Drug Facts

Active ingredients (in each softgel)	***Purposes***
Acetaminophen 325 mg	Pain reliever/fever reducer
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 & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & 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 8 softgels in 24 hours, which is the maximum daily amount for this product
- 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.

Ask a doctor before use if you have

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

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.

Directions

- take only as directed
- do not exceed 8 softgels per 24 hours

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

Other information

- store at 20-25°C (68-77°F)
- protect from light, heat and moisture

Inactive ingredients

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone K30, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

Questions?

Call toll free: **1-888-423-0139**

PRINCIPAL DISPLAY PANEL - 24 Softgel Blister Pack Carton

NDC: 36800-827-24

*Compare to the active ingredients
in Vicks® Nyquil™ Severe Cold & Flu

MAXIMUM STRENGTH RELIEF
Night Time
Cold & Flu Relief

SEVERE

PAIN RELIEVER-FEVER REDUCER - ACETAMINOPHEN
COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr
ANTIHISTAMINE - DOXYLAMINE SUCCINATE
NASAL DECONGESTANT - PHENYLEPHRINE HCl

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Sinus Congestion & Pressure
- Runny Nose & Sneezing • Cough

24 SOFTGELS

actual size

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*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® NyQuil™ Severe

CT3680082724

LOT:
EXP:

24 SOFTGELS

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Sinus Congestion & Pressure
- Runny Nose & Sneezing • Cough

Night Time
Cold & Flu Relief
SEVERE

PAIN RELIEVER-FEVER REDUCER - **ACETAMINOPHEN**
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NASAL DECONGESTANT - PHENYLEPHRINE HCl

MAXIMUM STRENGTH RELIEF

*Compare to the active ingredients in Vicks® NyQuil™ Severe Cold & Flu

NDC: 36800-827-24

0 36800 42328 2

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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COLD AND FLU SEVERE NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-848
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: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	Doxylamine Succinate	6.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C Blue NO. 1 (UNII: H3R47K3TBD)	
Gelatin, Unspecified (UNII: 2G86QN327L)	
Glycerin (UNII: PDC6A3C0OX)	
Polyethylene Glycol, Unspecified (UNII: 3WQ0SDW1A)	
Povidone K30 (UNII: U725QWY32X)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	789
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-848-24	2 in 1 CARTON	05/01/2021	

1		12 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	05/01/2021	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 1/2023 TOPCO ASSOCIATES LLC