SEVERE NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride capsule, gelatin coated
TopCo Associates LLC

SEVERE NIGHTTIME COLD AND FLU

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 4 doses 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

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.

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.

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 sleep

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 or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to 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

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. 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 4 doses per 24 hours

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

Other information

- store at room temperature

Inactive ingredients

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, shellac, sorbitol sorbitan, sodium hydroxide, titanium dioxide

Questions or comments?

Call toll free: **1-888-333-9792**

PRINCIPAL DISPLAY PANEL

Compare to Vicks® NyQuil® Severe Cold & Flu active ingredients

NIGHTTIME Severe Cold & Flu

ACETAMINOPHEN/ PAIN RELIEVER/ FEVER REDUCER

DEXTROMETHORPHAN HBR/ COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE/ ANTIHISTAMINE

PHENYLEPHRINE HCL/ NASAL DECONGESTANT

MAXIMUM STRENGTH

Relieves headache, fever, sore throat, minor aches & pains, nasal/sinus congestion & sinus
pressure, sneezing, runny nose & cough

24 SOFTGELS

SEVERE NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride capsule, gelatin coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-659
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	10 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 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 (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	116
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-659-24	2 in 1 CARTON	10/31/2019	
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 Drug	M012	10/31/2019	

Labeler - TopCo Associates LLC (006935977)

Revised: 12/2023 TopCo Associates LLC