NIGHTTIME COLD AND FLU MAX SOFTGELS- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled
Topco Associates, LLC

Nighttime Cold and Flu Max Softgels

Drug Facts

Active ingredient (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 15 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:
• cough due to minor throat & bronchial irritation
• sore throat
• headache• minor aches & pains• fever• runny nose & sneezing

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
• more than 8 Softgels in 24 hrs, which is the maximum daily amount for this product
• with other drugs containing acetaminophen
• 3 or more alcoholic drinks daily 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 •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 n 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, & tranquilizers may increase drowsiness

Stop use and ask a doctor if
• pain 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
• 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 (1-800-222-1222) right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

Directions

• **take only as directed • do not exceed 8 softgels per 24 hrs**
• adults & children 12 yrs & over 2 Softgels with water every 6 hrs
• children 4 to under 12 yrs ask a doctor
• children under 4 yrs do not use

Other information

• store between 20-25°C (68-77°F).
Avoid high humidity and excessive heat.
Protect from light.

Questions or comments?

1-800-373-6981 (toll-free)

Inactive ingredients

FD&C Blue No. 1, FD&C Red No. 40, FD&C Yellow No. 10, gelatin, glycerin, isopropyl alcohol, MCT Oil, polyethylene glycol-400, propylene glycol, povidone, purified water, silver sheen, sorbitol solution

Distributed by:
Topco Associates LLC
Itasca, IL 60143

PRINCIPAL DISPLAY PANEL

Nighttime
Cold & Flu Max
Softgels

Carton

NIGHTTIME COLD AND FLU MAX SOFTGELS

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76162-913
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	SD15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-913-24	2 in 1 CARTON	09/25/2024	
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	09/25/2024	

Labeler - Topco Associates, LLC (006935977)

Revised: 9/2024 Topco Associates, LLC