NIGHTTIME COLD AND FLU MAX SOFTGELS MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled
TOPCO ASSOCIATES LLC

NIGHTTIME

Cold and Flu Max

Softgels

MAXIMUM STRENGTH

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

• temporarily relieves these symptoms due to a cold or flu:
• minor aches and pains
• headache
• cough
• sore throat
• nasal and sinus congestion
• temporarily reduces fever

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 or severe allergic reactions. Symptoms may include:
• skin reddening
• blisters
• rash n hives
• facial swelling
• asthma (wheezing)
• shock
If a skin or general allergic 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 to sedate children.

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
• in children under 12 years of age

Ask a doctor before use if you have

• liver disease n heart disease n high blood pressure
• thyroid disease n diabetes
• cough with excessive phlegm (mucus)
• difficulty in urination due to enlargement of the prostate gland
• persistent or chronic cough such as occurs with smoking, asthma, or emphysema

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

• may cause marked drowsiness n avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• n excitability may occur, especially in children

Stop use and ask a doctor if

• pain, cough, or nasal congestion 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.
• nervousness, dizziness, or sleeplessness occurs
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. Quick 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 the recommended dose
• adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
• children under 12 years: do not use

Other information

• store at room temperature. Avoid temperatures above 25°C (77°F).

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, pearlin silver, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, titanium dioxide

Questions or comments?

1-888-423-0139

Carton

TopCare health

NDC 36800-732-24

COMPARE TO ALKA-SELTZER® PLUS®
MAXIMUM STRENGTH NIGHTTIME COLD & FLU

POWERMAXTM GELS ACTIVE INGREDIENTS

NIGHTTIME

Cold & Flu Max Softgels
MAXIMUM STRENGTH

PAIN RELIEVER-FEVER REDUCER - ACETAMINOPHEN

COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr

ANTIHISTAMINE - DOXYLAMINE SUCCINATE

NASAL DECONGESTANT - PHENYLEPHRINE HCl

RELIEVES:
• Nasal Congestion
• Cough
• Headache & Body Ache
• Sore Throat
• Runny Nose

•Smaller Capsule •Same Strength

24SOFTGELS**
**Liquid-Filled Capsules

Carton

NIGHTTIME COLD AND FLU MAX SOFTGELS MAXIMUM STRENGTH

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76162-732
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	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL ((oblong))	**Size**	16mm
Flavor		**Imprint Code**	106
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-732-24	2 in 1 CARTON	04/20/2022	
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	04/20/2022	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 12/2023 TOPCO ASSOCIATES LLC