

NON-DROWSY DAYTIME COLD AND FLU MAX SOFTGELS MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled
TOPCO ASSOCIATES LLC

NON-DROWSY DAYTIME

Cold and Flu Max

Softgels

MAXIMUM STRENGTH

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

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

- 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

When using this product do not exceed recommended dosage

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, pearl silver, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, titanium dioxide

Questions or comments?

1-888-423-0139

Carton

TopCare health

NDC 36800-720-24

COMPARE TO ALKA-SELTZER® PLUS®
MAXIMUM STRENGTH DAYTIME COLD & FLU
POWERMAX™ GELS ACTIVE INGREDIENTS*

NON-DROWSY DAYTIME

Cold & Flu Max Softgels
MAXIMUM STRENGTH

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

RELIEVES:

- Nasal Congestion
 - Cough
 - Headache & Body Ache
 - Sore Throat
 - Sinus Pressure
- Smaller Capsule •Same Strength

24SOFTGELS**

**Liquid-Filled Capsules

minis

Drug Facts
Active Ingredients (in each softgel)
 Acetaminophen 325 mg...Pain reliever/fever reducer
 Dextromethorphan...Cough suppressant
 Hydrobromide 10 mg...Cough suppressant
 Phenylephrine hydrochloride 5 mg...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 or 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 redness, hives, rash, blisters, 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 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, do not use in children under 12 years of age.

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 #8, gelatin, glycerin, pearlin silver, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, titanium dioxide

Questions or comments? 1-888-423-0130

Drug Facts (continued)
 Ask a doctor before use if you have liver disease, heart disease, high blood pressure, thyroid disease, 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. When using this product do not exceed recommended dosage. 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.

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

DISTRIBUTED BY
 TOPCO ASSOCIATES LLC
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 QUESTIONS? 1-888-423-0130
 topcare@topco.com
 www.topcarebrand.com
 MADE IN INDIA

Scan here for more information or call 1-888-423-0130

TopCare health
 NON-DROWSY DAYTIME
Cold & Flu Max Softgels
 MAXIMUM STRENGTH
 PAIN RELIEVER • FEVER REDUCER - ACETAMINOPHEN
 COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr
 NASAL DECONGESTANT - PHENYLEPHRINE HCl
RELIEVES:
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 • Cough
 • Headache & Body Ache
 • Sore Throat
 • Sinus Pressure
 •Smaller Capsule • Same Strength actual size
24 SOFTGELS**
 **Liquid-Filled Capsules
minis
 COMPARE TO ALKA-SALTZER PLUS® MAXIMUM STRENGTH DAYTIME COLD & FLU POWERMAX® GELS ACTIVE INGREDIENTS?
 NON-DROWSY DAYTIME
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 NASAL DECONGESTANT - PHENYLEPHRINE HCl

NON-DROWSY DAYTIME COLD AND FLU MAX SOFTGELS MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-720
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1VS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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	105
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-720-24	1 in 1 CARTON	04/20/2022	
1		24 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)