

**DAY AND NIGHT SEVERE SINUS CONGESTION AND COUGH MAXIMUM STRENGTH-
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine
hydrochloride**

PuraCap Pharmaceutical 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.

Day and Night Severe Sinus Congestion and Cough

Day Severe Sinus Congestion & Cough

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Night Sever Sinus Congestion & Cough

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

Purposes

Day Severe Sinus Congestion & Cough

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Purposes

Night Sever Sinus Congestion & Cough

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

Day Severe Sinus Congestion & Cough

- temporarily relieves these symptoms due to a cold or flu:
 - nasal congestion
 - sinus congestion and pressure
 - headache
 - minor aches and pains

- cough
- sore throat
- helps clear nasal passages and shrinks swollen membranes
- temporarily reduces fever

Uses

Night Severe Sinus Congestion & Cough

- temporarily relieves these symptoms due to a cold or flu:
 - nasal congestion
 - sinus congestion and pressure
 - headache
 - minor aches and pains
 - cough
 - sore throat
 - runny nose
 - sneezing
- helps clear nasal passages and shrinks swollen membranes
- temporarily reduces fever

Day Severe Sinus Congestion & Cough

Warnings

Liver warning

These products contain acetaminophen. Severe liver damage may occur if you take

- more than 10 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 or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- 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
- 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.

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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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- 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
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

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Day Severe Sinus Congestion & Cough**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

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Day Severe Sinus Congestion & Cough**Other information**

- Store at room temperature 15°-30°C (59°-86°F).

Night Severe Sinus Congestion & Cough**Other information**

- Store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat.

Day Severe Sinus Congestion & Cough**Inactive ingredients**

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white ink

Night Severe Sinus Congestion & Cough**Inactive ingredients**

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white ink

Day Severe Sinus Congestion & Cough**Questions or comments?**

Call toll free: 1-855-215-8180

Night Severe Sinus Congestion & Cough**Questions or comments?**

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PRINCIPAL DISPLAY PANEL

Day and Night Severe Sinus Congestion and Cough 20ct

NDC 51013-427-08

*Compare to the active ingredients in Alka-Seltzer Plus® Maximum Strength Severe Sinus Congestion & Cough Day & Night Liquid Gels

DO NOT TAKE THESE PRODUCTS AT THE SAME TIME

<p style="text-align: right;">DAY</p> <p>Drug Facts Maximum Strength Day Severe Sinus Congestion & Cough</p> <p>Active ingredients (in each softgel) Acetaminophen 325 mg - Pain reliever/fever reducer Dextromethorphan hydrobromide 10 mg - Cough suppressant Phenylephrine hydrochloride 5 mg - Nasal decongestant</p> <p>Uses Temporarily relieve these symptoms due to a cold or flu: nasal congestion ■ sinus congestion and pressure headache ■ minor aches and pains ■ cough sore throat ■ runny nose ■ sneezing helps clear nasal passages and drains swollen membranes temporarily reduces fever</p> <p>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 3 or more alcoholic drinks a day while using this product Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include skin redness ■ hives ■ skin swelling ■ asthma (wheezing) ■ shock medication right away: skin or eye allergic reaction occurs, stop use and seek medical help right away.</p>	<p style="text-align: right;">NIGHT</p> <p>Drug Facts Maximum Strength Night Severe Sinus Congestion & Cough</p> <p>Active ingredients (in each softgel) Acetaminophen 325 mg - Pain reliever/fever reducer Dextromethorphan hydrobromide 10 mg - Cough suppressant Doxylamine succinate 6.25 mg - Antihistamine Phenylephrine hydrochloride 5 mg - Nasal decongestant</p> <p>Uses Temporarily relieve these symptoms due to a cold or flu: nasal congestion ■ sinus congestion and pressure headache ■ minor aches and pains ■ cough ■ sore throat helps clear nasal passages and drains swollen membranes temporarily reduces fever</p> <p>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 3 or more alcoholic drinks a day while using this product Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include skin redness ■ hives ■ skin swelling ■ asthma (wheezing) ■ shock medication right away: skin or eye allergic reaction occurs, stop use and seek medical help right away.</p>
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Maximum Strength Severe Sinus Congestion & Cough

NDC 51013-427-08 *Compare to the active ingredients in Alka-Seltzer Plus®
Maximum Strength Severe Sinus Congestion
& Cough Day & Night Liquid Gels

Maximum Strength Severe Sinus Congestion & Cough

DAY NON-DROWSY

Acetaminophen 325 mg - Pain reliever/fever reducer
Dextromethorphan hydrobromide 10 mg - Cough suppressant
Phenylephrine hydrochloride 5 mg - Nasal decongestant

- Nasal & Sinus Congestion
- Sinus Pressure
- Headache & Body Ache
- Cough



8-16 SOFTGELS
(Liquid Filled Capsules)

NIGHT

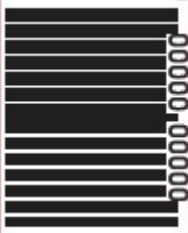
Acetaminophen 325 mg - Pain reliever/fever reducer
Dextromethorphan hydrobromide 10 mg - Cough suppressant
Doxylamine succinate 6.25 mg - Antihistamine
Phenylephrine hydrochloride 5 mg - Nasal decongestant

- Sinus Congestion & Pressure
- Headache & Pain
- Runny Nose & Sneezing
- Cough



8-16 SOFTGELS
(Liquid Filled Capsules)

0 00000 000000 0



KEEP OUTER CARTON FOR COMPLETE
WARNINGS AND PRODUCT INFORMATION

LOT NO. EXP. DATE

PARENTS:
Learn about them medicine about
www.StopMedicineAbuse.org

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

CMB66-00

Distributed by:
Company Name
Street Address
City, State Zip
Made in China
CMB66-00

Save Sinus Congestion & Cough Day & Night Liquid Gels

This product is not manufactured or distributed by Bayer HealthCare LLC, now rebranded as Max Strength. Maximum Strength

Maximum Strength Day Severe Sinus Congestion & Cough

Drug Facts (on blue)

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 within 48 hours of headache that lasts
 ■ these occur in a serious condition.
 ■ narcolepsy, dizziness, or sleepiness 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. Avoid alcohol and grapefruit juice while taking this medicine. Tell your doctor if you are taking any other medicines. Tell your doctor if you are taking any other medicines.

Directions
 ■ Do not take more than the recommended dose
 ■ adults and children 12 years of age 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 of age do not use

Other information
 ■ Store at room temperature 15°-30°C (59°-86°F).
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Inactive ingredients
 FD-Cresol #40, FD-Cresol #40, gelatin, glycerin, polyethylene glycol, polydimethylsiloxane, purified water, sodium acetate, sodium citrate, and white ink.

Questions or comments? Call toll free 1-XXX-XXX-XXXX

Maximum Strength Day Severe Sinus Congestion & Cough

Drug Facts (on blue)

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DAY AND NIGHT SEVERE SINUS CONGESTION AND COUGH MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-427

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-427-08	1 in 1 CARTON; Type 0: Not a Combination Product	02/08/2018	

Quantity of Parts			
Part #	Package Quantity	Total Product Quantity	
Part 1	1 BLISTER PACK	12	
Part 2	1 BLISTER PACK	8	

DAY SEVERE SINUS CONGESTION AND COUGH

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

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:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	orange (clear)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	PC9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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	02/08/2018	

Part 2 of 2

NIGHT SEVERE SINUS CONGESTION AND COUGH

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

Product Information

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:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 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, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green (clear)	Score	no score
Shape	capsule (oblong)	Size	21mm
Flavor		Imprint Code	PC22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		8 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	02/08/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/08/2018	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(51013-427) , analysis(51013-427)

Revised: 1/2020

PuraCap Pharmaceutical LLC