NON DROWSY DAYTIME AND NIGHTTIME SINUS CONGESTION AND COUGH RELIEF- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride
CVS PHARMACY, INC.

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.

Non Drowsy DAYTIME and NIGHTTIME Sinus Congestion and Cough Relief

Non Drowsy DAYTIME Sinus Congestion and Cough Relief
Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg
Phenylephrine hydrochloride 5 mg

NIGHTTIME Sinus Congestion and Cough Relief
Active ingredients (in each softgel)

Acetaminophen 325 mg
Dextromethorphan hydrobromide 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine hydrochloride 5 mg

Purposes

Non Drowsy DAYTIME Sinus Congestion and Cough Relief

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Purposes

Nighttime Sinus Congestion and Cough Relief

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

Non Drowsy DAYTIME Sinus Congestion and Cough Relief

- 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

Uses

NIghttime Sinus Congestion and Cough Relief

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

Non Drowsy DAYTIME Sinus Congestion and Cough Relief
Warnings

Liver warning

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

- more than 4000 mg of Acetaminophen 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.
- 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.

Nighttime Sinus Congestion and Cough Relief

Warnings

Liver warning

These products contain acetaminophen. Severe liver damage may occur if you take
- more than 4000 mg of Acetaminophen 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 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
- 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.

Non Drowsy DAYTIME Sinus Congestion and Cough Relief
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

Nighttime Sinus Congestion and Cough Relief
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

Non Drowsy DAYTIME Sinus Congestion and Cough Relief
Other information

- store at room temperature. Avoid excessive heat.

Nighttime Sinus Congestion and Cough Relief
Other information

- store at room temperature. Avoid excessive heat.

Non Drowsy DAYTIME Sinus Congestion and Cough Relief
Inactive ingredients

FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol-400, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Nighttime Sinus Congestion and Cough Relief
Inactive ingredients

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

Non Drowsy DAYTIME Sinus Congestion and Cough Relief

Questions or comments?1-888-333-9792

Nighttime Sinus Congestion and Cough Relief

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PRINCIPAL DISPLAY PANEL

CVS NON-DROWSY DAYTIME and NIGHTTIME Sinus Congestion and Cough Relief 20ct

Compare to the active ingredients in

Alka-Seltzer PLUS® Maximum Strength Severe Congestion & Cough Day & Night Liquid Gels*

Daytime NON-DROWSY

Sinus Congestion & Cough Releif

ACETAMINOPHEN- Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr - Cough suppressant

PHENYLEPHRINE HCI - Nasal decongestant

Relieves:

Nasal & Sinus congestion; Sinus Pressure; Headache & body ache; Cough

12 SOFTGELS

NIGHTTIME

Sinus Congestion & Cough Relief

ACETAMINOPHEN- Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr - Cough suppressant

DOXYLAMINE SUCCINATE - Antihistamine

PHENYLEPHRINE HCI - Nasal decongestant

Relieves:

Sinus Congestion & Pressure; Headache & pain; Runny nose & sneezing; Cough

8 SOFTGELS

20 TOTAL

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND

TAMPER-EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT

*This product is not manufactured or distributed by Bayer

Healthcare LLC, owner of the registered trademark

Alka-Seltzer PLUS® Maximum Strength Severe Sinus Contestion & Cough Day & Night Liquid Gels.

NON DROWSY DAYTIME AND NIGHTTIME SINUS CONGESTION AND COUGH RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-629

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-629-20	1 in 1 CARTON; Type 0: Not a Combination Product	02/11/2020	

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

Part 1 of 2

NON DROWSY DAYTIME SINUS CONGESTION AND COUGH RELIEF

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	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 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange (transparent)	Score	no score
Shape	CAPSULE (oblong)	Size	21mm
Flavor		Imprint Code	512

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	02/11/2020	

Part 2 of 2

NIGHTTIME SINUS CONGESTION AND COUGH RELIEF

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	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 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	green (transparent)	**Score**	no score
Shape	CAPSULE (oblong)	**Size**	21mm
Flavor		**Imprint Code**	116
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	02/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/11/2020	

Labeler - CVS PHARMACY, INC. (062312574)

Registrant - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PRIVATE LIMITED		677385498	manufacture(69842-629)

Revised: 2/2020 CVS PHARMACY, INC.