SEVERE SINUS CONGESTION AND COUGH DAYTIME NON-DROWSY / NIGHTIME- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride / acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride
Walgreens

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.

SEVERE SINUS CONGESTION AND COUGH

DAYTIME NON-DROWSY / NIGHTIME

SEVERE SINUS CONGESTION & COUGH DAYTIME SOFTGELS

Drug Facts

Active Ingredients (in each softgel)	***Purpose***
Acetaminophen 325 mg	Pain reliever / Fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

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

Warnings

Liver warning

This product contains 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 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.
- 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
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. 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

- take only as recommended (see overdose warning)
- do not take more than 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 excessive heat.

Inactive ingredients

FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

1-888-333-9792

SEVERE SINUS CONGESTION & COUGH NIGHTTIME SOFTGELS

Drug Facts

Active Ingredients (in each softgel)	***Purpose***
Acetaminophen 325 mg	Pain reliever / Fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

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

- sore throat
- runny nose
- sneezing
- temporarily reduces fever

Warnings

Liver warning

This product contains 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 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 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.
- in children under 12 years of age
- If you have ever had an allergic reaction to this product or any of its ingredients

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.

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 excessive heat.

Inactive ingredients

D&C Yellow #10, FD&C Blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

PRINCIPAL DISPLAY PANEL - Kit Carton

DAY & NIGHT PACK

NDC 0363-9890-20

Walgreens

Compare to Alka-Seltzer PLUS® Day and Night Severe Sinus Congestion & Cough active ingredients‡‡

DAYTIMENON-DROWSY

Severe Sinus
Congestion & Cough

ACETAMINOPHEN/

PAIN RELIEVER/FEVER REDUCER

DEXTROMETHORPHAN HBr/COUGH SUPPRESSANT

PHENYLEPHRINE HCL/NASAL CONGESTANT

- **Pain reliever, fever reducer,**

  cough suppressant &
  nasal decongestant

Actual Size

12 SOFTGELS

NIGHTTIME

Severe Sinus
Congestion & Cough

ACETAMINOPHEN/

PAIN RELIEVER/FEVER REDUCER

DEXTROMETHORPHAN HBr/COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE/ANTIHISTAMINE

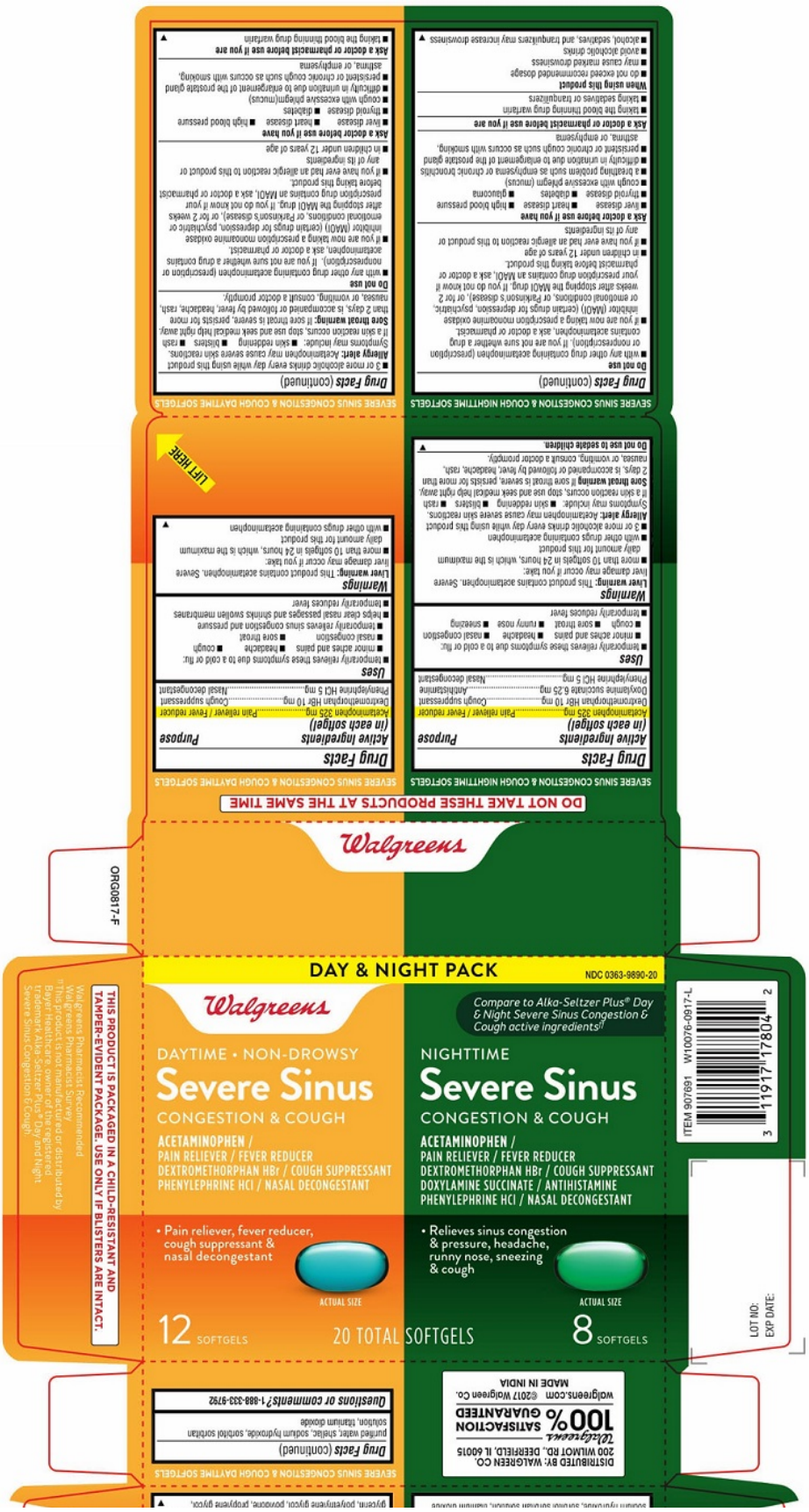
PHENYLEPHRINE HCL/NASAL DECONGESTANT

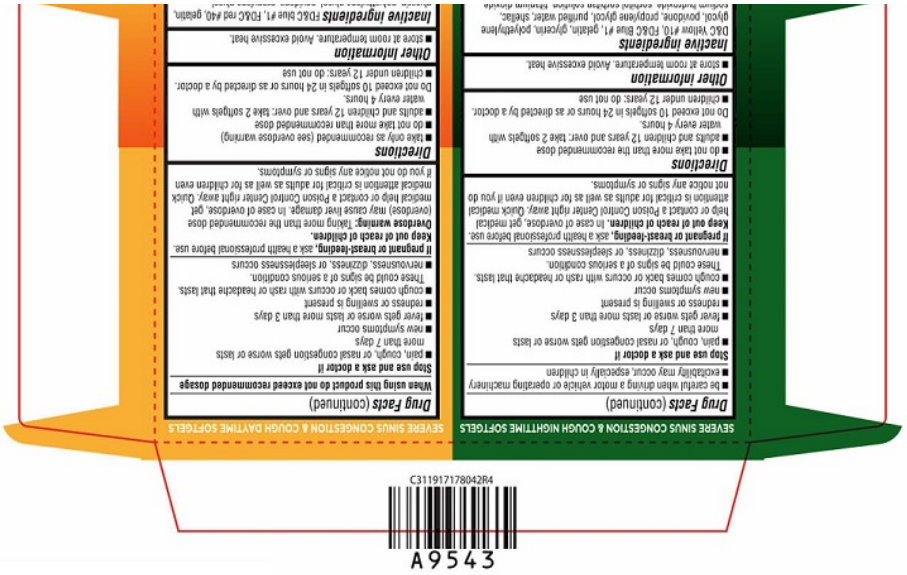
- **Relieves sinus congestion & pressure, headache, runny nose, sneezing & cough**

Actual Size

8 SOFTGELS

20 TOTAL SOFTGELS


DAY & NIGHT PACK
NDC 0363-9890-20
Walgreens
DAYTIME • NON-DROWSY
Severe Sinus
CONGESTION & COUGH
ACETAMINOPHEN /
PAIN RELIEVER / FEVER REDUCER
DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT
PHENYLEPHRINE HCl / NASAL DECONGESTANT
• Pain reliever, fever reducer, cough suppressant & nasal decongestant
ACTUAL SIZE
12 SOFTGELS
Compare to Alka-Seltzer Plus® Day & Night Severe Sinus Congestion & Cough active ingredients††
NIGHTTIME
Severe Sinus
CONGESTION & COUGH
ACETAMINOPHEN /
PAIN RELIEVER / FEVER REDUCER
DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT
DOXYLAMINE SUCCINATE / ANTIHISTAMINE
PHENYLEPHRINE HCl / NASAL DECONGESTANT
• Relieves sinus congestion & pressure, headache, runny nose, sneezing & cough
ACTUAL SIZE
8 SOFTGELS
20 TOTAL SOFTGELS
THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TAMPER-EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.
Walgreens Pharmacists Recommended
Walgreens is not manufactured or distributed by Bayer Healthcare, owner of the registered trademark Alka-Seltzer Plus® Day and Night Severe Sinus Congestion & Cough.
DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
Walgreens SATISFACTION 100% GUARANTEED
walgreens.com ©2017 Walgreen Co.
MADE IN INDIA
ITEM 907691 W10076-0917-L
LOT NO:
EXP DATE:
ORG0817-F
DO NOT TAKE THESE PRODUCTS AT THE SAME TIME
LIFT HERE
SEVERE SINUS CONGESTION & COUGH NIGHTTIME SOFTGELS
Drug Facts
Active Ingredients (in each softgel)
Purpose
Acetaminophen 325 mg — Pain reliever / Fever reducer
Dextromethorphan HBr 10 mg — Cough suppressant
Doxylamine succinate 6.25 mg — Antihistamine
Phenylephrine HCl 5 mg — Nasal decongestant
Uses
■ temporarily relieves these symptoms due to a cold or flu:
■ minor aches and pains ■ headache ■ nasal congestion
■ cough ■ sore throat ■ runny nose ■ sneezing
■ temporarily reduces fever
Warnings
Liver warning: This product contains 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 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 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.
■ in children under 12 years of age
■ if you have ever had an allergic reaction to this product or any of its ingredients
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
SEVERE SINUS CONGESTION & COUGH DAYTIME SOFTGELS
Drug Facts (continued)
■ 3 or more alcoholic drinks every day 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.
■ 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)
■ 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
Drug Facts (continued)
purified water, sorbitol, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide
Questions or comments? 1-888-333-9792
SEVERE SINUS CONGESTION & COUGH DAYTIME SOFTGELS
Drug Facts (continued)
glycerin, polyethylene glycol, povidone, propylene glycol, sodium hydroxide, sodium lauryl sulfate, titanium dioxide



SEVERE SINUS CONGESTION AND COUGH DAYTIME NON-DROWSY / NIGHTIME

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride / acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-9890

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9890-20	1 in 1 CARTON	12/15/2017	

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

SEVERE SINUS CONGESTION AND COUGH DAYTIME NON-DROWSY

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 BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL (OBLONG)	**Size**	20mm
Flavor		**Imprint Code**	314
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 not final	part343	08/15/2015	

Part 2 of 2

SEVERE SINUS CONGESTION AND COUGH NIGHTIME

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
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL (OBLONG)	**Size**	20mm
Flavor		**Imprint Code**	116
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

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 not final	part343	08/15/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/15/2015	

Labeler - Walgreens (008965063)

Registrant - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PVT LTD		677385498	manufacture(0363-9890)

Revised: 11/2021 Walgreens