WALGREENS MAXIMUM STRENGTH NON DROWSY DAY AND NIGHT COLD AND FLU- walgreens maximum strength non drowsy day and night cold and flu 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.

Walgreens Maximum Strength Non Drowsy Day and Night Cold & Flu

Do not take these products at the same time.

Drug Facts

Walgreens Non Drowsy Day Cold & Flu

Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

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 · 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 warfa

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

Directions

· do not take more than the recommended dose

· adults and children 12 years and over: take 2 capsules with water

every 4 hours. Do not exceed 10 capsules in 24 hours or as

directed by a doctor.

· children under 12 years: do not use

Other information

Other information

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

Inactive ingredients

FD&C yellow #6, gelatin,
glycerin, potassium aluminum silicate, polyethylene glycol, povidone,
propylene glycol, purified water, sorbitol , titanium
dioxide

Questions or comments?

Questions or comments? **1-888-333-9792**

Walgreens Maximum Strength Night Cold & Flu

Active ingredients (in each capsule)

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

Uses

· 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

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 · 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 ● 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

Directions

· do not take more than the recommended dose

· adults and children 12 years and over: take 2 capsules with water

every 4 hours. Do not exceed 10 capsules in 24 hours or as

directed by a doctor.

· children under 12 years: do not use

Other information

Other information

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

Inactive ingredients FD&C Blue #1, FD&C yellow
#10, gelatin, glycerin, potassium aluminum silicate, polyethylene glycol , povidone, propylene glycol, purified water, sorbitol
sorbitan solution, titanium dioxide

Questions or comments?

Questions or comments?**1-888-333-9792**

PRINCIPLA DISPLAY PANEL

WALGREENS MAXIMUM STRENGTH NON DROWSY DAY AND NIGHT COLD AND FLU

walgreens maximum strength non drowsy day and night cold and flu kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-5552

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-5552-24	1 in 1 CARTON; Type 0: Not a Combination Product	02/04/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	16
Part 2	1 BLISTER PACK	8 in 2

Part 1 of 2

MAXIMUM STRENGTH NON DROWSY DAYTIME COLD AND FLU

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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
WATER (UNII: 059QF0KO0R)	
POVIDONE (UNII: FZ989GH94E)	
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)	

Product Characteristics

Color	orange (Opaque)	**Score**	no score
Shape	OVAL (oblong)	**Size**	18mm
Flavor		**Imprint Code**	101
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph final	part341	02/04/2020	

Part 2 of 2

MAXIMUM STRENGTH NIGHTTIME COLD AND FLU

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
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SORBITAN (UNII: 6O92ICV9RU)	
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)	

Product Characteristics

Color	green (opaque)	**Score**	no score
Shape	OVAL (oblong)	**Size**	19mm
Flavor		**Imprint Code**	102
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	02/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/04/2020	

Labeler - Walgreens (008965063)

Registrant - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PVT LTD		677385498	manufacture(0363-5552)

Revised: 9/2022 Walgreens