DAYTIME NIGHTIME SEVERE COLD- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, diphenhydramine hydrochloride
CVS Pharmacy

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.

CVS Pharmacy, Inc. Daytime Nighttime Severe Cold Drug Facts

Active ingredients (in each caplet) DAY TIME COLD & FLU

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purposes - Day Time

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Active ingredients (in each caplet) NIGHT TIME COLD & FLU

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Purposes - Night Time

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- cough
- minor aches and pains
- headache
- nasal congestion
- sore throat
- sinus congestion and pressure
- runny nose **(NIGHT TIME only)**
- sneezing **(NIGHT TIME only)**

- itching of the nose or throat **(NIGHT TIME only)**
- itchy, watery eyes due to hay fever **(NIGHT TIME only)**
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive **(DAY TIME only)**
- controls cough to help you get to sleep
- temporarily reduces fever

Warnings

Liver warning: These products contain 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 these products

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.
- with any other product containing diphenhydramine, even one used on skin **(NIGHT TIME only)**
- 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 these products.
- if you have ever had an allergic reaction to these products or any of their ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- glaucoma **(NIGHT TIME only)**
- a breathing problem such as emphysema or chronic bronchitis **(NIGHT TIME only)**
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers **(NIGHT TIME only)**

When using these products

- **do not use more than directed**
- excitability may occur, especially in children **(NIGHT TIME only)**
- marked drowsiness may occur **(NIGHT TIME only)**
- alcohol, sedatives, and tranquilizers may increase drowsiness **(NIGHT TIME only)**
- avoid alcoholic drinks **(NIGHT TIME only)**
- be careful when driving a motor vehicle or operating machinery **(NIGHT TIME only)**

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough 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.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 directed (see Overdose warning)**
- do not take more than 10 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

Other information

- **each caplet contains:** sodium 4 mg **(DAY TIME COLD & FLU only)**
- store at 20-25°C (68-77°F)

Inactive ingredients (DAY TIME COLD & FLU)

croscarmellose sodium, crospovidone, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone,

pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Inactive ingredients (NIGHT TIME COLD & FLU)

crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredients in Mucinex® Fast-Max® Day Time & Night Time

MAXIMUM STRENGTH

Daytime

Severe Cold

Acetaminophen

Pain reliever, Fever reducer

Dextromethorphan HBr

Cough suppressant

Guaifenesin – Expectorant

Phenylephrine HCl

Nasal decongestant

MULTI-SYMPTOM

Controls cough

Thins & loosens mucus

Relieves nasal & chest congestion

Relieves aches, fever & sore throat

FOR AGES 12+

Actual Size

MAXIMUM STRENGTH

Nighttime

Severe Cold

Acetaminophen

Pain reliever, Fever reducer

Diphenhydramine HCl

Antihistamine, Cough Suppressant

Phenylephrine HCl

Nasal decongestant

MULTI-SYMPTOM

Controls cough

Relieves runny nose & sneezing

Relieves nasal congestion

Relieves aches, fever & sore throat

FOR AGES 12+

Actual Size

20 DAYTIME CAPLETS & 10 NIGHTTIME CAPLETS

TOTAL 30 CAPLETS

CVS Health

Compare to the active ingredients in Mucinex® Fast-Max® Day Time & Night Time*

MAXIMUM STRENGTH**

Daytime Severe Cold

Acetaminophen
Pain reliever, Fever reducer

Dextromethorphan HBr
Cough suppressant

Guaifenesin - Expectorant

Phenylephrine HCl
Nasal decongestant

MULTI-SYMPTOM

- Controls cough
- Thins & loosens mucus
- Relieves nasal & chest congestion
- Relieves aches, fever & sore throat

FOR AGES 12+
Actual Size

20 DAYTIME CAPLETS

MAXIMUM STRENGTH**

Nighttime Severe Cold

Acetaminophen
Pain reliever, Fever reducer

Diphenhydramine HCl
Antihistamine, Cough Suppressant

Phenylephrine HCl
Nasal decongestant

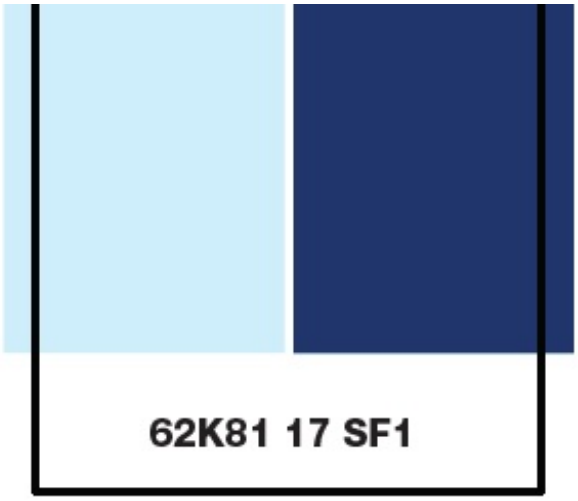
MULTI-SYMPTOM

- Controls cough
- Relieves runny nose & sneezing
- Relieves nasal congestion
- Relieves aches, fever & sore throat

FOR AGES 12+
Actual Size

& **10 NIGHTTIME CAPLETS**

TOTAL 30 CAPLETS


62K81 17 SF1

Do not take DAY TIME COLD & FLU and NIGHT TIME COLD & FLU caplets at the same time. Always wait at least 4 hours before taking another dose. Do not take more than a total of 10 caplets in any 24-hour period. Take only as directed.

Drug Facts

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Active ingredients (in each caplet) DAY TIME COLD & FLU	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Active ingredients (in each caplet) NIGHT TIME COLD & FLU	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Diphenhydramine HCl 12.5 mg	Antihistamine/cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses ■ temporarily relieves these common cold and flu symptoms:
- ■ minor aches and pains
- ■ headache
- ■ nasal congestion
- ■ sore throat
- ■ sinus congestion and pressure
- ■ cough
- ■ runny nose *(NIGHT TIME only)*
- ■ sneezing *(NIGHT TIME only)*
- ■ itching of the nose or throat *(NIGHT TIME only)*
- ■ itchy, watery eyes due to hay fever *(NIGHT TIME only)*
- ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive *(DAY TIME only)*
- ■ controls cough to help you get to sleep
- ■ temporarily reduces fever

Warnings

Liver warning: These products contain 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 these products

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. ▶

#181292

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: L2K81 17 B1

PEEL BACK HERE

Drug Facts (continued)

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. ■ with any other product containing diphenhydramine, even one used on skin *(NIGHT TIME only)* ■ 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 these products. ■ if you have ever had an allergic reaction to these products or any of their ingredients

Ask a doctor before use if you have ■ liver disease ■ heart disease ■ diabetes ■ high blood pressure ■ thyroid disease ■ trouble urinating due to an enlarged prostate gland ■ glaucoma *(NIGHT TIME only)* ■ a breathing problem such as emphysema or chronic bronchitis *(NIGHT TIME only)* ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are
■ taking the blood thinning drug warfarin
■ taking sedatives or tranquilizers *(NIGHT TIME only)*

When using these products ■ **do not use more than directed**
■ excitability may occur, especially in children *(NIGHT TIME only)*
■ marked drowsiness may occur *(NIGHT TIME only)* ■ alcohol, sedatives, and tranquilizers may increase drowsiness *(NIGHT TIME only)*
■ avoid alcoholic drinks *(NIGHT TIME only)* ■ be careful when driving a motor vehicle or operating machinery *(NIGHT TIME only)* ▼

Drug Facts (continued)

Stop use and ask a doctor if
- ■ nervousness, dizziness, or sleeplessness occur
- ■ pain, nasal congestion or cough 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.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 directed (see Overdose warning)**
- ■ do not take more than 10 caplets in any 24-hour period
- ■ adults and children 12 years of age and over: take 2 caplets every 4 hours
- ■ children under 12 years of age: do not use

Other information
- ■ **each caplet contains:** sodium 4 mg *(DAY TIME COLD & FLU only)*
- ■ store at 20-25°C (68-77°F)

Inactive ingredients (DAY TIME COLD & FLU)
croscarmellose sodium, crospovidone, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Inactive ingredients (NIGHT TIME COLD & FLU)
crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments? 1-800-719-9260

DAYTIME NIGHTIME SEVERE COLD

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, diphenhydramine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-736

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69842-736-81	1 in 1 CARTON; Type 0: Not a Combination Product	12/17/2019	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	10 BLISTER PACK	20
Part 2	5 BLISTER PACK	10

Part 1 of 2

DAYTIME SEVERE COLD

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, film coated

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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	RED	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	L922
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 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		

Part 2 of 2

NIGHTTIME SEVERE COLD

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride tablet, film coated

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
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	L27H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/17/2019	

Labeler - CVS Pharmacy (062312574)

Revised: 4/2020 CVS Pharmacy