DAYTIME NIGHTTIME COLD/FLU - acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl
Velocity Pharma

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.

Acetaminophen, Dextromethorphan and Phenylephrine Day time Cold and Flu

Active Ingredient

(in each softgel) of daytime cold and flu

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

(in each softgel) of nighttime cold and flu

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine Succinate 6.25 mg

Purpose

Daytime Cold and Flu:

pain reliever

Cough Suppressant

Nasal decongestant

Nighttime cold and flu purpose:

pain reliever

Cough Suppressant

Antihistamine

Uses

Daytime cold and flu: pain reliever, cough suppressant and Nasal decongestant

NightTime Cold and Flu: pain reliever, cough suppressant and Antihistamine

Warnings

Warnings Failure to follow these warnings could result in serious consequences.

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hours which is maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

do not use:

- with any other drug containing acetaminophen (prescription or not prescription). 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.

Ask a doctor before use if you have

- liver disease
- Heart disease
- Thyroid disease
- Diabetes
- High blood pressure
- Trouble urinating due to enlarged prostate gland

ask your doctor or pharmacist before use if you are taking the blood thinning drug warfarin.
When using this product, do not use more than directed.
Stop use and ask a doctor if:

- Redness or swelling is present
- You get nervous, dizzy or sleepless
- Fever gets worse or lasts more than 3 days
- New symptoms occur
- Symptoms do not get better within 7 days or are accompanied by a fever

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

Overdose warning: **Taking more than recommended dose (overdose) may cause liver damage.** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Tamper evident: this package is safety sealed and child resistant. Use only if blisters are intact. If difficult to open use scissors.

Keep out of reach of children.

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

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Direction

Daytime Cold and Flu:

- **do not exceed 4 doses per 24 hours**
- **take only as directed – see overdose warning**
- **Adults and children 12 years and over:** 2 softgels with water every 4 hours
- **children under 12 years:** ask a doctor
- **Children under 4 years:** do not use

NightTime Cold and Flu

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- **take only as directed – see overdose warning**
- **Adults and children 12 years and over:** 2 softgels with water every 4 hours
- **children under 12 years:** ask a doctor
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Other Information

- store at room temperature

Inactive Ingredients

Daytime:

FD&C Red No.40, FD&C Yellow No. 6, Gelatin, Glycerin, Poyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sorbitol Special, Titanium dioxide

NightTime:

FD&C Blue No.1, FD&C Yellow No. 6, Gelatin, Glycerin, Poyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sorbitol Special, Titanium dioxide, glycerin

Questions or Comments

Call toll free 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL


DayTime
Cold and Flu
Non Drowsy
Multi Symptom
NDC 76168-057-12
NightTime
Cold and Flu
All Night
Cold & Flu Relief
2-PACK
SUPER VALUE
SUPER VALUE
2-PACK
COMBO PACK:
• Non Drowsy Multi Symptom and
• All Night Cold & Flu Relief
Compare to the active ingredient in Vicks® DayQuil®*
Compare to the active ingredient in Vicks® NyQuil®*
DayTime
Cold and Flu
Non Drowsy
8
Softgels
MULTI SYMPTOM RELIEF
✓ Aches and Fever - Acetaminophen
✓ Cough - Dextromethorphan HBr
✓ Nasal Congestion - Phenylephrine Hcl
NightTime
Cold and Flu
4
Softgels
MULTI SYMPTOM RELIEF
✓ Aches and Fever - Acetaminophen
✓ Cough - Dextromethorphan HBr
✓ Sneezing, Runny Nose - Doxylamine Succinate
Drug Facts (for DayTime)
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
Drug Facts (for Night Time)
Active ingredients (in each softgel) Purpose
Acetaminophen 325 mg.....Pain reliever/Fever reducer
Dextromethorphan HBr 15 mg .....Cough suppressant
Doxylamine Succinate 6.25 mg.....Antihistamine
LOT :
EXP :
Directions
■ Do not exceed 4 doses per 24 hours.
■ Take only as directed - see Overdose warning
Adults and Children 12 years and over: 2 softgels with water every 4 hours
Children 4 to under 12 years: ask a doctor
Children under 4 years: do not use
"This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® and Vicks NyQuil®
Distributed by VELOCITY PHARMA LLC
226 B Sherwood Avenue, Farmingdale, NY 11735
Mfg.Lic.No. : MF-DRUGS-25-04/2011
76168 05712

80x70x28mm

NDC: 76168-057-12 12 softgels, 8 DayTime Cold and Flu, 4 NightTime Cold and Flu

DAYTIME NIGHTTIME COLD/FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76168-057

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76168-057-12	1 in 1 CARTON		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	8
Part 2	1 BLISTER PACK	4

Part 1 of 2

DAYTIME COLD AND FLU

acetaminophen,dextromethorphan,phenylephrine capsule, liquid filled

Product Information	
Item Code (Source)	NDC:76168-055
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)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	ORANGE	**Score**	no score
Shape	CAPSULE	**Size**	22mm
Flavor		**Imprint Code**	512
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		

Part 2 of 2

NIGHTTIME COLD AND FLU

acetaminophen,dextromethorphan,doxylamine capsule, liquid filled

Product Information	
Item Code (Source)	NDC:76168-056
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

Inactive Ingredients

Ingredient Name	Strength

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	CAPSULE	**Size**	22mm
Flavor		**Imprint Code**	215
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 BLISTER PACK		

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	07/15/2014	

Labeler - Velocity Pharma (962198409)

Registrant - Velocity Pharma (962198409)

Revised: 7/2014 Velocity Pharma