

DAYTIME COLD AND FLU - acetaminophen,dextromethorphan,phenylephrine capsule, liquid filled

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)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

pain reliever

Cough Suppressant

Nasal decongestant

Uses

pain reliever, cough suppressant and Nasal decongestant

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

Keep out of reach of children.

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.

Direction

- **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

Other Information

- store at room temperature

Inactive Ingredients

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

Questions or Comments

Call toll free 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

VELDPAK12C

Distributed by
VELOCITY PHARMA LLC
226 B Sherman Avenue, Farmingdale, NY 11735
This product not manufactured or distributed by Procter & Gamble
distributor of Vicksi[®] DayTime



MULTI SYMPTOM RELIEF
✓ Aches and Fever - Acetaminophen
✓ Cough - Dextromethorphan HBr
✓ Nasal Congestion -
Phenylephrine HCl



DayTime
Cold and Flu

DayTime
Cold and Flu

NDC 76168-055-02

Compare to the active
ingredient in Vicksi[®]
DayTime

Inactive ingredients
FD&C Red No. 40, FD&C Yellow No. 6, Gelatin, Glycerin, Polyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sorbitol Special, Titanium Dioxide
Other information
Store at room temperature.
Questions call: 1-855-314-1850

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

Drug Facts
Active ingredients (in each softgel)
Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg
Purpose
Pain reliever
Cough suppressant
Nasal decongestant

Drug Facts (continued)
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 the 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 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.
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 a 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
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 can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults and 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.

C31 01

NDC: 76168-055-02 12 softgels

DAYTIME COLD AND FLU

acetaminophen,dextromethorphan,phenylephrine capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	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	NDC:76168-055-02	12 in 1 BLISTER PACK		
1		1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2014	

Labeler - Velocity Pharma (962198409)

Registrant - Velocity Pharma (962198409)

Revised: 4/2014

Velocity Pharma