SEVER DAYTIME COLD AND FLU AND SEVER NIGHTTIME COLD AND FLU-
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, guaifenesin, phenylephrine hydrochloride
Kmart Corporation

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.

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sever daytime cold & flu and sever nighttime cold & flu

Active ingredients (in each softgel)

DAYTIME SEVERE COLD AND FLU

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5mg

Active ingredients (in each softgel)

NIGHTTIME SEVERE COLD AND FLU

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5mg

Purpose

DAYTIME SEVERE COLD AND FLU

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Purposes

NIGHTTIME SEVERE COLD AND FLU

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep (**Nighttime only**)
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing (**Nighttime only**)

- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take
- more than 4 doses in 24 hrs, 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

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.

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.

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.
- to make a child sleep (**Nighttime only**)

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema (**Daytime only**)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema (**Nighttime only**)
- glaucoma (**Nighttime only**)

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

When using this product
- **do not use more than directed**

Nighttime only:
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if
- you get nervous, dizzy or sleepless
- 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

Taking more than directed can cause serious health problems. 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
- take only as directed - see **Overdose warning**
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs and over	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

- **when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing**

Other information

- store at room temperature 15º-30ºC (59º-86ºF)and avoid excessive heat

Inactive ingredients

DAYTIME SEVERE COLD AND FLU

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

Inactive ingredients

NIGHTTIME SEVERE COLD AND FLU

FD&C blue #1, D&C yellow #10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

Questions or comments?

Call toll free: **1-800-842-7886**

Principal Display Panel - Carton Label

Severe daytime cold & flu and severe nighttime cold & flu 24ct

NDC 49738-036-04

*Compare to the active ingredients in Vicks® DayQuil® Severe and NyQuil® Severe Cold and Flu

THIS PRODUCT IS PACKAGED IN A CHILDRES STAR T AND TAMPEREVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT

smart sense®

COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® DAYQUIL® SEVERE COLD AND FLU†

SEE NEW WARNINGS

ACTUAL SIZE

severe daytime cold & flu

MAXIMUM STRENGTH RELIEF

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, GUAIFENESIN, PHENYLEPHRINE HCl

PAIN RELIEVER / FEVER REDUCER, COUGH SUPPRESSANT, EXPECTORANT, NASAL DECONGESTANT

NON-DROWSY

ALCOHOL FREE

ANTIHISTAMINE FREE

RELIEVES:

ACHES • FEVER
COUGH • NASAL CONGESTION
SORE THROAT

12 SOFTGELS

49738-036-04

smart sense®

COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® NYQUIL® SEVERE COLD AND FLU†

ACTUAL SIZE

severe nighttime cold & flu

MAXIMUM STRENGTH RELIEF

ACETAMINOPHEN, DEXTROMETHORPHAN HBr, DOXYLAMINE SUCCINATE, PHENYLEPHRINE HCl

PAIN RELIEVER / FEVER REDUCER, COUGH SUPPRESSANT, ANTIHISTAMINE, NASAL DECONGESTANT

ALCOHOL FREE

RELIEVES:

ACHES • FEVER
SORE THROAT • SNEEZING
RUNNY NOSE • COUGH

12 SOFTGELS

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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Distributed by: Kmart Corporation
Hoffman Estates, IL 60179
Shop kmart.com
Made in China

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil® Severe Cold & Flu and Vicks® NyQuil® Severe Cold & Flu.

LOT NO:

EXP DATE:

DO NOT TAKE THESE PRODUCTS AT THE SAME TIME

KMD 4-00

Drug Facts

Active Ingredients for Daytime (In each softgel)	Purpose
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 for Nighttime (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

SEVER DAYTIME COLD AND FLU AND SEVER NIGHTTIME COLD AND FLU

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49738-036

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49738-036-04	1 in 1 CARTON; Type 0: Not a Combination Product	07/12/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	12

Part 1 of 2

SEVERE DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, 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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	orange (clear)	**Score**	no score
Shape	capsule (oblong)	**Size**	26mm
Flavor		**Imprint Code**	PC26
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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 final	part341	07/12/2017	

Part 2 of 2

SEVERE 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	5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green	**Score**	no score
Shape	capsule (oblong)	**Size**	21mm
Flavor		**Imprint Code**	PC22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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 final	part341	07/12/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/12/2017	

Labeler - Kmart Corporation (008965873)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(49738-036) , analysis(49738-036)

Revised: 11/2019 Kmart Corporation