DAYTIME COLD AND FLU AND NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, 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.

daytime cold & Flu and nighttime cold & flu

COLD & FLU FORMULA DAY NON-DROWSY Active ingredients (in each softgel)

Acetaminophen 325 mg Dextromethorphan hydrobromide 10 mg Phenylephrine hydrochloride 5 mg

COLD & FLU FORMULA NIGHT Active ingredients (in each softgel)

Acetaminophen 325 mg Dextromethorphan hydrobromide 10 mg Doxylamine succinate 6.25 mg Phenylephrine hydrochloride 5 mg

Purposes

DAY COLD & FLU FORMULA

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Purposes

NIGHT COLD & FLU FORMULA

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:
 - minor aches and pains
 - headache
 - cough
 - sore throat
 - nasal and sinus congestion
 - runny nose and sneezing (Nighttime only)

• temporarily reduces fever

Warnings

Liver warning

These products contain acetaminophen. Severe liver damage may occur if you take

- more than 10 softgels in 24 hours, 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 to sedate children. (Nighttime only)

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
- diabetes
- thyroid disease
- 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
- glaucoma (Nighttime only)
- a breathing problem such as emphysema or chronic bronchitis (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 exceed recommended dosage

In addition when using Nighttime:

- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- exitability 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 (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 the recommended dose
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- children under 12 years: do not use

Other information

• store at room temperature 15°-30°C (59°-86°F). Avoid excessive heat (Nighttime only).

DAY COLD & FLU FORMULA Inactive ingredients

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

NIGHTTIME COLD & FLU FORMULA Inactive ingredients

D&C yellow #10, FD&C blue #1, 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

Daytime cold & flu and nighttime cold & flu 20 ct

NDC 49738-037-08

*Compare to the active ingredients in Alka-Seltzer PLUS[®] Day and Night Cold and Flu Formula



Questions or comments? Calitonities: 1-800-842-7886						
inactive ingredients v ightime: D&C yellow #10, FD&C blue#1, gelatin, giycerin, polyethyleneglycid, povidome, propylene glycol, purified vater, sorbibol sorbiban solution, and whiteeidble ink						
inactive ingredients Dayrime . FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povi done, propyleneglycid, purified waler, sorbibli sorbibin solution, and whiteedble ink						
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	Drug Facts (continued)					
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These could be signs of a serious condition. menorousness, dizziness, or slee plessnes s occurs I pregrent or breachteeding , ask a health protessional before use. Keep out or teac hol children . in case of over dose, get medical help or contact a PoisonC ontrol Center in case of over dose, get medical help or contact a PoisonC ontrol Center in case of over dose, get medical help or contact a PoisonC ontrol Center in the out or the contact a PoisonC ontrol Center in the out over the out of the out on the out in the out of the out of the out of the out of the out in the out of the out a well as for children even if y ou do not not ice a ny signs or symptoms. as well as for children even if y ou do not not ice a ny signs or symptoms.	Invitinanty other drugs ontaining ass baring op hen (press ription or nompress cription). If youare not sure whether a drug contains asstand option as sk a doctor or press citizens ostatistics as the cost of up contains as the cost of up on a nom a citizens. If youare not sure whether a drug contains asstand option (certain pharma cist. Intyou are not sking a prescription monoamine oxidas in hib for (NOADI) (certain drugs for depression, psychiatric, or emotioned contains, out drugs for depression, psychiatric, or emotional conditions, or Parkinson a contains of the set of the structure of the set of the conditions (contains as a disease), or tor 2 weeks after stopping the M a dio disease), or tor 2 weeks after stopping the M a dio disease), or tor 2 weeks after stopping the set of conditions, or the notating appression, or tor 2 weeks after stopping the M a dio disease), or tor 2 weeks after stopping the M a dio disease), or tor 2 weeks after stopping the M a dio disease), or tor 2 weeks after stopping the M a dio disease), or tor 2 weeks after stopping the M a dio disease atter stopping the M a disease atter stopping the module.					
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(Mghttime only) A sk a doctor or pharma cist befor euse it you a re making the blood thim ingdrug war tarin making ug sedat vesor tra rquilizers (Nighttim e only)	Warn ings Liver war ing: These products contain ace taminophen. Severe liver da mage may oc cur if you take more than 10s of the lin24 hours, which is the maximum daily amount for					
Drug Facts (continued) cough with excessive phlegm (mucus) acough with excessive phlegm (mucus) aditticuity in unination due to enlargem entot the prostale gland aditticuity in unination due to enlargem entot the prostale gland aditticuity in unination due to enlargem entot the prostale gland or emphysem a glaucoma (Mghttime only) or emphysem a or chronic thron of the aditticuity or oble m such as emphysem a or chronic thron of the mathematical second	Drug Facts (continued) Uses minor aches and pains = treatache = c cugh = sore throat minor aches and pains = treatache = c cugh = sore throat miscal and sinus congestion = muny nose and sneezing (Nightfm e only) miscal hy reduces fever emporently reduces fever					

DAYTIME COLD AND FLU AND NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Pr	Product Information					
Pro	duct Type	HUMAN OTC DRUG	Item Code (Source)		NDC:49738-037	
Pa	ckaging					
#	Item Code	Package Description		Marketing Start Da	te Marketing End Date	
1 N	DC:49738-037-08	1 in 1 CARTON; Type 0: Not a Combin	ation Product	07/12/2017		
0	Quantity of Parts					
-						
Par	t #	Package Quantity	Total Product Quantity			
Par	1 1 BLISTER PAC	K	12			

Part 1 of 2

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: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE	5 mg		
Inactive Ingredients				

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6092ICV9RU)	

Product Characteristics				
Color	orange (clear)	Score	no score	
Shape	capsule (oblong)	Size	20 mm	
Flavor		Imprint Code	PC9	
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 Infor	mation					
Marketing Category Application Number or Monograph Citation Mark			keting Start Date	Marketing	End Date	
OTC monograph final part341 07/12/2			/2017			
Part 2 of 2						
NIGHTTIME CO acetaminophen, dextro liquid filled		D FLU PLUS n hydrobromide, doxylamin	e succinate, j	ohenylephrine hydro	ochloride ca	apsule,
Product Information	n					
Route of Administration	n	ORAL				
Active Ingredient/A	ctive Moie	ety				
	Ingre	edient Name		Basis of Stre	ength	Strength
ACETAMINOPHEN (UNII:	362O9ITL9I) (ACETAMINOPHEN - UNII:362	2O9ITL9D)	ACETAMINOPHEN		325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH)DEXTROMETHORPHAN PUNII: 7355X3ROTS)(DEXTROMETHORPHAN - UNII: 7355X3ROTS)HYDROBROMIDE					IAN	10 mg
PHENYLEPHRINE HYDRO CHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - PHENYLEPHRINE UNII:1WS297W6 MV) PHENYLEPHRINE				5 mg		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) DOXYLAMINE SUCCIN			CINATE	6.25 mg		
Inactive Ingredients	5					
		Ingredient Name			St	rength
D&C YELLOW NO. 10 (U	JNII: 35SW5U	•				5
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)						
GELATIN (UNII: 2G86QN3	327L)					
GLYCERIN (UNII: PDC6A3	3C0OX)					
POLYETHYLENE GLYCO	DL, UNSPEC	IFIED (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ9890	GH94E)					
PROPYLENE GLYCOL (U	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
WATER (UNII: 059QF0KO	00R)					
SORBITOL (UNII: 506T60	0A25R)					
SORBITAN (UNII: 6092ICV9RU)						
Product Characteris	stics					
Color	or green (clear) Score no			no score		
Shape	capsule (obl	blong) Size 21mm			21mm	
Flavor		Imprint Code PC2			PC22	
Contains						

Packaging	Packaging					
# Item Code		Package Description	Marketing Start Date	Marketing End Date		
1	1 in 1 C	ARTON				
1	8 in 1 B	LISTER PACK; Type 0: Not a Combination Product				
Marketing Information						
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Dat						
OTC monograph	TC monograph final part341		07/12/2017			
Marketing Information						
Marketing Ca	tegory	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(49738-037) , analysis(49738-037)

Revised: 11/2019

Kmart Corporation