DAYTIME NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, phenylephrine hcl and acetaminophen, dextromethorphan hbr, doxylamine succinate WALGREENS

695T 0363 0729 WALGREENS - Daytime Nighttime Cold & Flu

DRUG FACTS

Daytime Cold & Flu *Active ingredients (in each softgel)* Acetaminophen 325 mg Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg

Nighttime Cold & Flu Active ingredients (in each softgel)

Acetaminophen 325 mg Dextromethorphan HBr 15 mg Doxylamine succinate 6.25 mg

Daytime Cold & Flu *Purpose*

Pain reliever/fever reducer Cough suppressant Nasal decongestant

Nighttime Cold & Flu *Purpose*

Pain reliever/fever reducer Cough suppressant Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion (Daytime only)
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing (Nighttime only)

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
- wilh 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.

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 (Daytime only)
- high blood pressure (Daytime only)
- thyroid disease (Daytime only)
- diabetes (Daytime only)
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema (Daytime only)
- glaucoma (Nighttime only)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma,chronic bronchitis or emphysema (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 (Daytime only)
- excitability may occur, especially in children (Nighttime only)
- marked drowsiness may occur (Nighttime only)
- avoid alcoholic drinks (Nighttime only)
- be careful when driving a motor vehicle or operating machinery (Nighttime only)
- alcohol, sedatives, & tranquilizers may increase drowsiness (Nighttime only)

Stop use and ask a doctor If

- you get nervous, dizzy or sleepless (Daytime only)
- pain, nasal congestion or cough get worse or last more than 7days (Daytime only)
- 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.
- pain, or cough gets worse or lasts more than 7days (Nighttime only)
- 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.

In case of overdose, get medical help or contact a Poison Control Center righl away (1-800-222-1222). Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

Directions

- take only as directed
- do not exceed 4 doses per 24 hrs

adults & children 12yrs & over: 2 softgels with water every 6 hrs(Nighttime only) 2 softgels with water every 4 hrs (Daytime only) children 4 to under 12 yrs: ask a doctor children under 4 yrs: do not use

OTHER INFORMATION

Other information

• store at room temperature

Inactive ingredients (Daytime only)

FD&C red # 40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide. *Inactive ingredients* (Nighttime only)

FD&C blue #1, FD&C yellow #10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide.

Questions? Call 1-877-290-4008



DAYTIME NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl and acetaminophen, dextromethorphan hbr, doxylamine succinate kit

Product Infor	mation						
Product Type	HUMAN	HUMAN OTC DRUG Item Code (S		ource)	NDC:0363-	0729	
Packaging							
# Item Code	Pa	ckage Description		Marketing St Date		Marketing End Date	
1 NDC:0363-0729- 24	2 in 1 CARTON		10)/15/2021			
1	1 in 1 BLISTER Product	1 BLISTER PACK; Type 0: Not a Combination duct					
Quantity of P	arts						
Part # Package Quantity				Total Produ	ct Quantity		
Part 1			8				
Part 2			4				
-	-	FLU orphan hbr pheny	/lphrine hcl ca	osule, liquid fi	lled		
DAYTIME C acetaminophine Product Infor	edextromethe	-	/lphrine hcl ca	osule, liquid fil	lled		
acetaminophine	e dextromethe	-	/lphrine hcl ca	osule, liquid fi	lled		
acetaminophine	rmation	orphan hbr pheny	/lphrine hcl ca	osule, liquid fil	lled		
acetaminophine Product Infor Item Code (Sou	rmation	orphan hbr pheny NDC:0363-0853	/lphrine hcl ca	osule, liquid fil	lled		
acetaminophine Product Infor Item Code (Sou Route of Admin	e dextromether rmation rce) istration	orphan hbr pheny NDC:0363-0853 ORAL	/lphrine hcl ca	osule, liquid fil	lled		
acetaminophine Product Infor Item Code (Sou Route of Admin	e dextromether mation rce) istration	orphan hbr pheny NDC:0363-0853 ORAL	/lphrine hcl ca		lled of Strength	Strengt	
acetaminophine Product Infor Item Code (Sou Route of Admin Active Ingred	e dextromether mation rce) istration ient/Active Ingree	NDC:0363-0853 ORAL Moiety dient Name -9D) (ACETAMINOPHEN	N - UNII:36209ITL	Basis	of Strength	Strengt 325 mg	
acetaminophine Product Infor Item Code (Sou Route of Admin Active Ingred ACETAMINOPHEN DEXTROMETHORPH	e dextromether mation rce) istration ient/Active ingree (UNII: 36209ITL PHAN HYDROBI IAN - UNII:7355X	NDC:0363-0853 ORAL Moiety dient Name -9D) (ACETAMINOPHEN ROMIDE (UNII: 9D2RT (3ROTS)	N - UNII:362O9ITL [19KYH]	9D) ACETAMINC DEXTROME HYDROBRO	of Strength DPHEN THORPHAN	_	
acetaminophine Product Infor Item Code (Sou Route of Admin Active Ingred ACETAMINOPHEN DEXTROMETHORPH	e dextromether mation rce) istration ient/Active ingree (UNII: 36209ITL PHAN HYDROBI IAN - UNII:7355X HYDROCHLORI	NDC:0363-0853 ORAL Moiety dient Name .9D) (ACETAMINOPHEN ROMIDE (UNII: 9D2RT	N - UNII:362O9ITL [19KYH]	9D) ACETAMINC DEXTROME HYDROBRO	of Strength OPHEN THORPHAN OMIDE HRINE	325 mg	
acetaminophine Product Infor Item Code (Sou Route of Admin Active Ingred ACETAMINOPHEN DEXTROMETHORPH (DEXTROMETHORPH PHENYLEPHRINE	e dextromether mation rce) istration ient/Active ingree (UNII: 36209ITL PHAN HYDROBI IAN - UNII:7355X HYDROCHLORI	NDC:0363-0853 ORAL Moiety dient Name -9D) (ACETAMINOPHEN ROMIDE (UNII: 9D2RT (3ROTS)	N - UNII:362O9ITL [19KYH]	9D) ACETAMINC DEXTROME HYDROBRO E - PHENYLEPH	of Strength OPHEN THORPHAN OMIDE HRINE	325 mg 10 mg	
acetaminophine Product Infor Item Code (Sou Route of Admin Active Ingred ACETAMINOPHEN DEXTROMETHORPH (DEXTROMETHORPH PHENYLEPHRINE	e dextromether mation rce) istration ient/Active ingree (UNII: 36209ITL PHAN HYDROBI IAN - UNII:7355X HYDROCHLORI	NDC:0363-0853 ORAL Moiety dient Name -9D) (ACETAMINOPHEN ROMIDE (UNII: 9D2RT (3ROTS)	N - UNII:362O9ITL [19KYH]	9D) ACETAMINC DEXTROME HYDROBRO E - PHENYLEPH	of Strength OPHEN THORPHAN OMIDE HRINE	325 mg 10 mg	
acetaminophine Product Infor Item Code (Sou Route of Admin Active Ingred ACETAMINOPHEN DEXTROMETHORF (DEXTROMETHORF (DEXTROMETHORF UNII: 1WS 297W6MV) Inactive Ingre	e dextromethe mation rce) istration ient/Active Ingree (UNII: 36209ITL PHAN HYDROBI AN - UNII:7355X HYDROCHLORI edients	NDC:0363-0853 ORAL Moiety dient Name 9D) (ACETAMINOPHEN ROMIDE (UNII: 9D2RT (3ROTS) DE (UNII: 04JA59TNSJ DE (UNII: 04JA59TNSJ	N - UNII:362O9ITL ГI9KYH)) (PHENYLEPHRIN	9D) ACETAMINC DEXTROME HYDROBRO E - PHENYLEPH	of Strength DPHEN THORPHAN DMIDE HRINE ORIDE	325 mg 10 mg	
acetaminophine Product Infor Item Code (Sou Route of Admin Active Ingred Active Ingred ACETAMINOPHEN DEXTROMETHORPH PHENYLEPHRINE I UNII: 1WS 297W6MV) Inactive Ingre FD&C RED NO. 40	e dextromethe mation rce) istration ient/Active lingree (UNII: 36209ITL PHAN HYDROBI MAN - UNII:7355X HYDROCHLORI edients	NDC:0363-0853 ORAL Moiety dient Name 9D) (ACETAMINOPHEN ROMIDE (UNII: 9D2RT (3ROTS) DE (UNII: 04JA59TNSJ DE (UNII: 04JA59TNSJ	N - UNII:362O9ITL FI9KYH)) (PHENYLEPHRIN	9D) ACETAMINC DEXTROME HYDROBRO E - PHENYLEPH	of Strength DPHEN THORPHAN DMIDE HRINE ORIDE	10 mg 5 mg	

POVIDONE (UNII: FZ98							
SORBITAN (UNII: 6092							
TITANIUM DIOXIDE (U FD&C YELLOW NO. 6							
SHELLAC (UNII: 46N10	•	EI95A0)					
WATER (UNII: 059QF0k							
GELATIN (UNII: 2G86Q							
GLYCERIN (UNII: PDC6							
PROPYLENE GLYCOL		Q167V3)					
Product Charact	teristics						
Color	orange		Score		no sc	ore	
Shape			Size		21mm	21mm	
Flavor		· ·	Imprint	Code	70		
Contains							
Marketing In	format	ion					
Marketing Category	Applicat	tion Number or Monograpl Citation	h Ma	rketing Start Date		ting End ate	
OTC Monograph Drug	M012		10/15	5/2021			
NIGHTTIME C acetaminophen de		ND FLU orphan hbr doxylamine succ	cinate ca	apsule, liquid fille	d		
Product Informa	ation						
		NDC:0363-0850					
Route of Administr							
Route of Administr	ration	ORAL					
Active Ingredien	t/Active	Moiety					
		dient Name		Basis of Stre	angth	Strength	
DEXTROMETHORPHA (DEXTROMETHORPHAN	N HYDROBI	ROMIDE (UNII: 9D2RTI9KYH)		DEXTROMETHORPH HYDROBROMIDE	-		
					15 mg		
	NII: 36209ITL	.9D) (ACETAMINOPHEN - UNII:362	O9ITL9D)	ACETAMINOPHEN		-	
DOXYLAMINE SUCCIN		9D) (ACETAMINOPHEN - UNII:362 /9BI9B5YI2) (DOXYLAMINE -	O9ITL9D)	ACETAMINOPHEN DOXYLAMINE SUCC	INATE	325 mg 6.25 mg	
			O9ITL9D)		INATE	325 mg	
DOXYLAMINE SUCCIN	NATE (UNII:)		O9ITL9D)		INATE	325 mg	
DOXYLAMINE SUCCIN UNII:95QB77JKPL)	NATE (UNII:)		O9ITL9D)			325 mg	
DOXYLAMINE SUCCIN UNII:95QB77JKPL)	NATE (UNII:) ents	/9BI9B5YI2) (DOXYLAMINE - Ingredient Name	O9ITL9D)			325 mg 6.25 mg	

POVIDONE (UNII: FZ 9 WATER (UNII: 059QF0			
SHELLAC (UNII: 46N10	· ·		
TITANIUM DIOXIDE (,		
PROPYLENE GLYCOL			
SORBITAN (UNII: 609	· · ·		
D&C YELLOW NO. 10			
GLYCERIN (UNII: PDC)			
	,		
Product Charac			
Color	green	Score	no score
Shape	OVAL (Oblong shaped)	Size	21mm
Flavor		Imprint Code	71
Contains			
Marketing In	formation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/15/2021	
Marketing In	formation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/15/2021	

Labeler - WALGREENS (008965063)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment						
Name	Address	ID/FEI	Business Operations			
MARKSANS PHARMA LIMITED		925822975	manufacture(0363-0729)			

Revised: 3/2024

WALGREENS