DAYTIME NIGHTTIME COLD/FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl AGILE PHARMACHEM

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 15 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 <u>acetaminophen</u>. 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 <u>acetaminophen</u> (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
 NightTime Cold and Flu: Warnings Failure to follow these warnings could result in serious consequences.

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- Heart disease
- Thyroid disease
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- 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

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.

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

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
- 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 controlled temperature of 59°F to 86°F(15°C to 30°C)
- Protect from direct sun light /Moisture/Freezing

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

Each soft gelatin cap Night Time Cold & Flu: - A		thorphan Hydrobromide US	P 15 mg & Doxylamine Succinate USP 6.25 mg
Day Time Cold & Flu: - Ace	etaminophen USP 325 mg, Dextrometh	orphan Hydrobromide USP	P 10 mg & Phenylephrine HCI USP 5 mg
BATCH NO.		QUANTITY	36X12 cartons of combopack
MFG.DATE	- (j.	SHIPPER NO.	out of
EXP.DATE		GROSS WT.	
-	-	NET WT.	
WARNING: KEEP OU CHILDREN	T OF THE REACH OF	STORE AT COM to 86°F (15°C to	NTROLLED TEMPERATURE OF 59°F 30°C)
CONFORMANCE WIT REGULATIONS THER	H THE F.D & C. ACT AND REUNDER.	PROTECT FRO FREEZING	M DIRECT SUNLIGHT / MOISTURE /
MANUFACTURED BY MEDGEL PRIVATE LI 19-20, SEZ, PHARMA PITHAMPUR, DISTT.	MITED ZONE, PHASE-II,	AGILE PHARMA 116D, SHIROMA SATELLITE, AH	ACHEM
MFG. LIC. NO.	: MP/DRUGS/25/04/2011	MFG. LIC. NO.	: GJ-AD2-98783
LABELLER CODE	51344	NDC No.	58805-004-12
SHIPPED TO: VELOCITY PHARMA I 226/B, SHERWOOD A FARMINGDALE, NY-1	VE,		
NDC No.	76168-057-12		

	Acetaminophen USP 325 mg, Dextromet		P 15 mg & Doxylamine Succinate USP 6.25 mg
Day Time Cold & Flu: - A	Acetaminophen USP 325 mg, Dextromet	horphan Hydrobromide USP	' 10 mg & Phenylephrine HCI USP 5 mg
BATCH NO.		QUANTITY	18X12 cartons of combo pack
MFG.DATE		SHIPPER NO.	out of
EXP.DATE		GROSS WT.	
(*)	-	NET WT.	
WARNING: KEEP O	UT OF THE REACH OF	STORE AT CON to 86°F (15°C to	ITROLLED TEMPERATURE OF 59°F 30°C)
CONFORMANCE W REGULATIONS THE	TH THE F.D & C. ACT AND REUNDER.	PROTECT FROM FREEZING	M DIRECT SUNLIGHT / MOISTURE /
MANUFACTURED E MEDGEL PRIVATE 19-20, SEZ, PHARM PITHAMPUR, DISTI	LIMITED A ZONE, PHASE-II,	DISTRIBUTED E AGILE PHARMA 116D, SHIROMA SATELLITE, AHI	CHEM
MFG. LIC. NO.	MP/DRUGS/25/04/2011	MFG. LIC. NO.	GJ-AD2-98783
LABELLER CODE	51344	NDC No.	58805-004-18
SHIPPED TO: VELOCITY PHARMA 226/B, SHERWOOD FARMINGDALE, NY	AVE,		
NDC No.	76168-057-12		

			P 15 mg & Doxytamine Succinate USP 6.25 mg 10 mg & Phenylephrine HCI USP 5 mg
BUTOU NO.			
BATCH NO.		QUANTITY	16X30 cartons of combo pack
MFG.DATE		SHIPPER NO.	out of
EXP.DATE		GROSS WT.	
¥	1	NET WT.	
WARNING: KEEP O	UT OF THE REACH OF	STORE AT CON to 86°F (15°C to	TROLLED TEMPERATURE OF 59°F 30°C)
CONFORMANCE W REGULATIONS THE	ITH THE F.D & C. ACT AND REUNDER.	PROTECT FROM FREEZING	M DIRECT SUNLIGHT / MOISTURE
MANUFACTURED E MEDGEL PRIVATE I 19-20, SEZ, PHARM PITHAMPUR, DISTT	IMITED A ZONE, PHASE-II,	DISTRIBUTED E AGILE PHARMA 116D, SHIROMA SATELLITE, AHI	CHEM
MFG. LIC. NO.	MP/DRUGS/25/04/2011	MFG. LIC. NO.	GJ-AD2-98783
LABELLER CODE	51344	NDC No.	58805-004-16
SHIPPED TO: VELOCITY PHARMA 226/B, SHERWOOD FARMINGDALE, NY	AVE,		
NDC No.	76168-057-12		

NDC: 58805-004-12 12 softgels, 8 DayTime Cold and Flu, 4 NightTime Cold and Flu
NDC: 58805-004-16 12 softgels, 8 DayTime Cold and Flu, 4 NightTime Cold and Flu
NDC: 58805-004-18 12 softgels, 8 DayTime Cold and Flu, 4 NightTime Cold and Flu

DAYTIME NIGHTTIME COLD/FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Produ	uct Information			
Produ	ct T yp e	HUMAN OTC DRUG	Item Code (Source)	NDC:58805-004
Packa	iging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC	58805-004-12	1 in 1 CARTON	08/01/2014	
2 NDC	58805-004-16	1 in 1 CARTON	08/01/2014	
3 NDC	58805-004-18	1 in 1 CARTON	08/01/2014	
Quant	tity of Parts			
Part #	Pa	ckage Quantity	Total Produ	ct 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)	NI

Route of Administration

NDC:76168-055 ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6 MV)	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)	
PO VIDO NE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Cha	racteristic	s			
Color		orange	Score		no score
Shape		CAPSULE	Size		22mm
Flavor			Imprint Code		512
Contains					
Packaging					
# Item Code		Package Description	L	Marketing Start Date	Marketing End Date
1	8 in 1 BLISTE	R PACK; Type 1: Convenience	Kit of Co-Package		
Marketing	g Informa	ition			

Marketing Ca	legory	Applicatio	n Number or Mon	ograph Citation	Marketing Start Date	Marketin	ig Ella Date
OTC monograph	final J	part341					
Part 2 of 2)						
Part 2 01 2							
NIGHTTI	ME C	OLD AN	D FLU				
acetaminophe	n,dextro	methorphar	,doxylamine caps	ule, liquid filled			
	.•						
Product Info		n					
Item Code (Source) NDC:76168-056 Dente of A durining transform ODAL							
Route of Administration ORAL							
Active Ingre	dient/A	ctive Moi	ety				
		Ingre	dient Name		Basis of St	trength	Strengt
ACETAMINOPH	IEN (UNII:	362O9ITL9I) (ACETAMINOPHEN	N - UNII:36209ITL9D)	ACETAMINOPHEN	J	325 mg
DEXTROMETH (DEXTROMETHO			MIDE (UNII: 9D2RTI	9 KYH)	DEXTROMETHOR HYDROBROMIDE	PHAN	15 mg
			,	MINE - UNII 950 B77 IA	(PL) DOXYLAMINE SU	CCINATE	6.25 mg
Inactive Ing	redients	5					
Inactive Ing	redients	5				C.	
			Ingredient N			St	rength
FD&C BLUE NO). 1 (UNII:	H3R47K3TBI))			St	rength
FD&C BLUE NO FD&C YELLOW	D. 1 (UNII: V NO. 6 (U	H3R47K3TBI JNII: H77VEI9))			St	rength
FD&C BLUE NO FD&C YELLOW GELATIN (UNII:). 1 (UNII: V NO. 6 (U 2G86QN	H3R47K3TBI JNII: H77VEI9 327L)))			St	rength
FD&C BLUE NO FD&C YELLOW GELATIN (UNII: POLYETHYLEN). 1 (UNII: V NO. 6 (U 2G86QN NE GLYCO	H3R47K3TBI JNII: H77VEI9 327L) OL 1000 (UN)) 3A8)			St	rength
FD&C BLUE NO FD&C YELLOW GELATIN (UNII:). 1 (UNII: V NO. 6 (U 2G86QN IE GLYC III: FZ989	H3R47K3TBI JNII: H77VEI9 327L) OL 1000 (UN GH94E)	D) 3A8) II: U076Q6Q621)			St	rength
FD&C BLUE NO FD&C YELLOW GELATIN (UNII: POLYETHYLEN POVIDONE (UN), 1 (UNII: V NO, 6 (U 2G86QN NE GLYCO III: FZ9890 LYCOL (1	H3R47K3TBI JNII: H77VEI9 327L) OL 1000 (UN GH94E) UNII: 6DC9Q	D) 3A8) II: U076Q6Q621)			St	rength
FD&C BLUE NO FD&C YELLO W GELATIN (UNII: POLYETHYLEN POVIDONE (UN PROPYLENE GI). 1 (UNII: 2G86QN NE GLYCO III: FZ9890 LYCOL (1 III: 506T6	H3R47K3TBI JNII: H77VEI9 327L) DL 1000 (UN GH94E) UNII: 6 DC9 Q 0 A25R)	D) 3A8) II: U076Q6Q621) I67V3)			St	rength
FD&C BLUE NO FD&C YELLOW GELATIN (UNII: POLYETHYLEN POVIDONE (UN PROPYLENE GJ SORBITOL (UN). 1 (UNII: 2G86QN IE GLYCO III: FZ9890 LYCOL (1 III: 506T6 XIDE (UN	H3R47K3TBI JNII: H77VEI9 327L) OL 1000 (UN GH94E) UNII: 6 DC9 Q 0 A25R) II: 15FIX9 V2J	D) 3A8) II: U076Q6Q621) I67V3)			St	rength
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FD&C BLUE NO FD&C YELLOW GELATIN (UNII: POLYETHYLEN POVIDONE (UN PROPYLENE GI SORBITOL (UN TITANIUM DIO GLYCERIN (UN	D. 1 (UNII: 2G86QN NE GLYCO III: FZ9890 LYCOL (1 III: 506T6 XIDE (UN II: PDC6A	H3R47K3TBI JNII: H77VEI9 327L) OL 1000 (UN GH94E) UNII: 6 DC9 Q 0 A25R) II: 15FIX9 V2J 3C0 O X)	D) 3A8) II: U076Q6Q621) I67V3)			St	rength
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FD&C BLUE NO FD&C YELLOW GELATIN (UNII: POLYETHYLEN POVIDONE (UN PROPYLENE GI SORBITOL (UN TITANIUM DIO GLYCERIN (UN Product Cha Color Shape Flavor Contains	D. 1 (UNII: 2G86QN NE GLYCO III: FZ9890 LYCOL (1 III: 506T6 XIDE (UN II: PDC6A	H3R47K3TBI JNII: H77VE19 327L) DL 1000 (UN GH94E) UNII: 6 DC9 Q 0 A25R) II: 15FIX9 V2J 3C0 OX) stics green	D) 3A8) II: U076Q6Q621) I67V3) P)	lame Score Size		Image: Normal State Image: Norma	rength
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		
Marketing Info	rmation		
Marketing Info Marketing Category	rmation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - AGILE PHARMACHEM (650687853)

Registrant - VELOCITY PHARMA (962198409)

Establishme	Establishment						
Name	Address	ID/FEI	Business Operations				
medgel		677385498	manufacture(58805-004)				

Revised: 9/2017

AGILE PHARMACHEM