

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 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

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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.

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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
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 - **take only as directed – see overdose warning**
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 - **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, Polyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sorbitol Special, Titanium dioxide

NightTime:

FD&C Blue No.1, FD&C Yellow No. 6, Gelatin, Glycerin, Polyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sorbitol Special, Titanium dioxide, glycerin

Questions or Comments

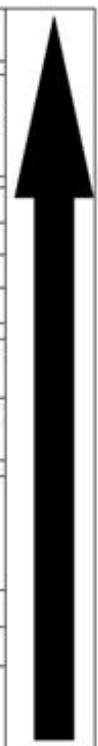
Call toll free 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Day Time Cold & Flu With Night Time Cold & Flu Soft Gels (Combopack)			
Each soft gelatin capsule Contains:			
<u>Night Time Cold & Flu:</u> - Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 15 mg & Doxylamine Succinate USP 6.25 mg			
<u>Day Time Cold & Flu:</u> - Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 10 mg & Phenylephrine HCl USP 5 mg			
BATCH NO.		QUANTITY	36X12 cartons of combopack
MFG.DATE		SHIPPER NO.	___ out of ___
EXP.DATE		GROSS WT.	
-	-	NET WT.	
WARNING: KEEP OUT OF THE REACH OF CHILDREN		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86°F (15°C to 30°C)	
CONFORMANCE WITH THE F.D & C. ACT AND REGULATIONS THEREUNDER.		PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING	
MANUFACTURED BY: MEDGEL PRIVATE LIMITED 19-20, SEZ, PHARMA ZONE, PHASE-II, PITHAMPUR, DISTT. DHAR-454775		DISTRIBUTED BY: AGILE PHARMACHEM 116D, SHIROMANI COMPLEX SATELLITE, AHMEDABAD-380015	
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 LLC 226/B, SHERWOOD AVE, FARMINGDALE, NY-11735			
NDC No.	76168-057-12		



Day Time Cold & Flu With Night Time Cold & Flu Soft Gels (Combo pack)			
Each soft gelatin capsule Contains:			
<u>Night Time Cold & Flu:</u> - Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 15 mg & Doxylamine Succinate USP 6.25 mg			
<u>Day Time Cold & Flu:</u> - Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 10 mg & Phenylephrine HCl 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 OUT OF THE REACH OF CHILDREN		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86°F (15°C to 30°C)	
CONFORMANCE WITH THE F.D & C. ACT AND REGULATIONS THEREUNDER.		PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING	
MANUFACTURED BY: MEDGEL PRIVATE LIMITED 19-20, SEZ, PHARMA ZONE, PHASE-II, PITHAMPUR, DISTT. DHAR-454775		DISTRIBUTED BY: AGILE PHARMACHEM 116D, SHIROMANI COMPLEX SATELLITE, AHMEDABAD-380015	
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 LLC 226/B, SHERWOOD AVE, FARMINGDALE, NY-11735			
NDC No.	76168-057-12		



Day Time Cold & Flu With Night Time Cold & Flu Soft Gels (Combo pack)			
Each soft gelatin capsule Contains:			
Night Time Cold & Flu: - Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 15 mg & Doxylamine Succinate USP 6.25 mg			
Day Time Cold & Flu: - Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 10 mg & Phenylephrine HCl USP 5 mg			
BATCH NO.		QUANTITY	16X30 cartons of combo pack
MFG.DATE		SHIPPER NO.	___ out of ___
EXP.DATE		GROSS WT.	
-	-	NET WT.	
WARNING: KEEP OUT OF THE REACH OF CHILDREN		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86°F (15°C to 30°C)	
CONFORMANCE WITH THE F.D & C. ACT AND REGULATIONS THEREUNDER.		PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING	
MANUFACTURED BY: MEDGEL PRIVATE LIMITED 19-20, SEZ, PHARMA ZONE, PHASE-II, PITHAMPUR, DISTT. DHAR-454775		DISTRIBUTED BY: AGILE PHARMACHEM 116D, SHIROMANI COMPLEX SATELLITE, AHMEDABAD-380015	
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 LLC 226/B, SHERWOOD AVE, FARMINGDALE, NY-11735			
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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58805-004
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Packaging

#	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	

Quantity of Parts

Part #	Package Quantity	Total Product 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) 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		8 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		

Part 2 of 2

NIGHTTIME COLD AND FLU

acetaminophen,dextromethorphan,doxylamine capsule, liquid filled

Product Information

Item Code (Source)	NDC:76168-056
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	215
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2014	

Labeler - AGILE PHARMACHEM (650687853)

Registrant - VELOCITY PHARMA (962198409)

Establishment

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

Revised: 9/2017

AGILE PHARMACHEM