

**ACETAMINOPHEN, DEXTROMETHORPHAN, DOXYLAMINE-
acetaminophen, dextromethorphan, doxylamine capsule, liquid filled
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 Doxylamine Night time Cold and Flu

Active Ingredient

(in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine Succinate 6.25 mg

Purpose

pain reliever

Cough Suppressant

Antihistamine

Uses

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

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

- **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 room temperature

Inactive Ingredients

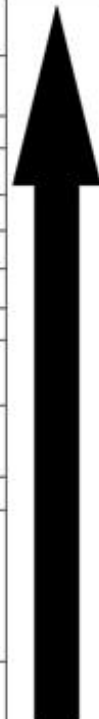
FD&C Red No.40, FD&C Yellow No. 6, Gelatin, Glycerin, Polyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sorbitol Special, Titanium dioxide

Questions or Comments

Call toll free 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Acetaminophen, Dextromethorphan HBr & Doxylamine Succinate Capsules			
Each soft gelatin capsule contains: Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 15 mg, Doxylamine Succinate USP 6.25 mg			
BATCH NO.		QUANTITY	32X20X12 softgels
MFG.DATE		SHIPPER NO.	
EXP.DATE		GROSS WT.	
NDC NO.	58805-003-14	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	
DISTRIBUTED BY: AGILE PHARMACHEM 116D, SHIROMANI COMPLEX SATELLITE, AHMEDABAD-380015		DISTRIBUTED TO: VELOCITY PHARMA LLC 226/B, SHERWOOD AVE, FARMINGDALE, NY-11735	
LABELLER CODE : 58805		LABELLER CODE : 76168	
MFG. LIC. NO. : GJ-AD2-98783			



Acetaminophen, Dextromethorphan Hydrobromide & Doxylamine Succinate Soft Gel Capsules			
Each soft gelatin capsule Contains: Acetaminophen USP..... 325 mg, Dextromethorphan Hydrobromide USP..... 15 mg, Doxylamine Succinate USP6.25 mg & Excipients..... QS			
BATCH NO.		QUANTITY	12X15X04 softgels
MFG.DATE		SHIPPER NO.	_____ out of _____
EXP.DATE		GROSS WT.	
NDC NO.	58805-003-04	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/25/4/2011	MFG. LIC. NO.	GJ-AD2-98783
LABELLER CODE	51344	LABELLER CODE	58805
SHIPPED TO: VELOCITY PHARMA LLC 226/B, SHERWOOD AVE, FARMINGDALE, NY-11735			
LABELLER CODE	76168		



NDC: 58805-003-14 and 58805-003-04

ACETAMINOPHEN, DEXTROMETHORPHAN, DOXYLAMINE

acetaminophen, dextromethorphan, doxylamine capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58805-003
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Route of Administration	ORAL
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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

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	NDC:58805-003-14	7680 in 1 BLISTER PACK	05/01/2014	
1		1 in 1 CARTON; Type 0: Not a Combination Product		
2	NDC:58805-003-04	180 in 1 BLISTER PACK	05/01/2014	
2		1 in 1 CARTON; 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	05/01/2014	

Labeler - Agile Pharmachem (650687853)

Registrant - Agile Pharmachem (650687853)

