ACETAMINOPHEN,DEXTROMETHORPHAN,PHENYLEPHRINE - acetaminophen,dextromethorphan,phenylephrine 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 Phenylephrine Day time Cold and Flu

Active Ingredient

(in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

pain reliever

Cough Suppressant

Nasal decongestant

Uses

pain reliever, cough suppressant and Nasal decongestant

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, Poyethylene 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 & Phenylephrine HCl Capsules			
Each soft gelatin capsule contains: Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 10 mg, Phenylephrine HCl USP 5 mg			
BATCH NO.		QUANTITY	32X20X12 softgels
MFG.DATE		SHIPPER NO.	
EXP.DATE		GROSS WT.	
NDC NO.	58805-002-14	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, Phenylephrine Hydrochloride & Dextromethorphan Hydrobromide Soft Gel Capsules			
Each soft gelatin capsule Contains: Acetaminophen USP..... 325 mg, Dextromethorphan Hydrobromide USP..... 10 mg, Phenylephrine HCl USP..... 5 mg & Excipients.....QS			
BATCH NO.		QUANTITY	12X15X08 softgels
MFG.DATE		SHIPPER NO.	_____ out of _____
EXP.DATE		GROSS WT.	
NDC NO.	58805 -002-08	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: 58805-002-14 , 58805-002-08

ACETAMINOPHEN,DEXTROMETHORPHAN,PHENYLEPHRINE

acetaminophen,dextromethorphan,phenylephrine capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58805-002

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	NDC:58805-002-14	7680 in 1 BLISTER PACK		
1		1 in 1 CARTON		
2	NDC:58805-002-08	8 in 1 BLISTER PACK		
2		180 in 1 CARTON		

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)