ACETAMINOPHEN DEXTROMETHORPHAN HBR GUAIFENESIN PHENYLEPHRINE HCL- acetaminophen dextromethorphan hbr guaifenes in phenylephrine hcl tablet, coated Strive Pharmaceuticals Inc.

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.

DGH MS Mucus Relief Cold & Flu Acetaminophen 325mg, Dextromethorphan HBr 10mg, Guaifenes in 200mg, Phenylephrine HCl 5mg

Acetaminophen 325mg

Dextromethorphan HBr 10mg

Guaifenesin 200mg

Phenylephrine HCl 5mg

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

colloidal silicon dioxide, croscarmellose sodium, di-calcium phosphate, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

- do not take more than directed (see overdose warning)
- do not take more than 12 caplets in any 24 hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use
- temporarily relieves these common cold and flu symptoms: *headache *cough *minor aches and pains *sore throat *sinus congestion and pressure
- tempoararily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 12 capltes in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drink daily while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin raction occurs, stop use and seek medical help right away.

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
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a 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

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts. 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.

Overdose Warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adult as well as for children even if you do not notice any signs or symptoms.

Keep out of reach of children.

Overdose Warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adult as well as for children even if you do not notice any signs or symptoms.

- store between 20-25°C (68-77°F).
- avoid excessive heat, light and humidity.





ACETAMINOPHEN DEXTROMETHORPHAN HBR GUAIFENESIN PHENYLEPHRINE HCL

acetaminophen dextromethorphan hbr guaifenesin phenylephrine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-133
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 O L 1HH48)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CALCIUM PHO SPHATE (UNII: 97Z1WI3NDX)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		

Product Characteristics				
Color	red	Score	no score	
Shape	CAPSULE	Size	20 mm	
Flavor		Imprint Code	S719	
Contains				

Pac	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

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1 NDC:70692-133-82	8 in 1 PACKAGE; Type 0: Not a Combination Product	07/10/2019		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	07/10/2019		

Labeler - Strive Pharmaceuticals Inc. (080028013)

Revised: 11/2020 Strive Pharmaceuticals Inc.