

**MAXIMUM STRENGTH COLD AND FLU- acetaminophen,dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled  
FAMILY DOLLAR SERVICES**

*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.*

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**628T FAMILY DOLLAR - 628T MAXIMUM STRENGTH COLD AND FLU 55319-628**

***Active ingredients (in each softgel)***

**Acetaminophen 325 mg**

Dextromethorphan HBr 10mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

- temporarily relieves these common cold and flu symptoms:

nasal congestion

headache

cough

minor aches and pains

sore throat

- temporarily reduces fever
- promotes nasal and/or sinus drainage
- 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 softgels in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

**Allergy alert**

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction 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.

- 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.
- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to 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)

taking the blood thinning drug warfarin.

### **do not use more than directed.**

#### 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 adults as well as for children even if you do not notice any signs or symptoms.

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- 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 rash or headache that lasts. These could be signs of a serious condition.

### **Directions**

- **Do not take more than directed (see Overdose warning)**
- do not exceed more than 12 softgels in any 24-hour period
- adults and children 12 years of age and over: take 2 softgels every 4 hours

- children under 12 years of age: do not use

## OTHER INFORMATION

- store at 20-25°C (68-77°F)
- avoid excessive heat

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide



## MAXIMUM STRENGTH COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-628
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	78
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-628-16	16 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/24/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/24/2020	

**Labeler** - FAMILY DOLLAR SERVICES (024472631)

**Registrant** - TIME CAP LABORATORIES, INC. (037052099)

### Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(55319-628)