

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

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

Drug Facts

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

Uses

- temporarily relieves these common cold and flu symptoms:

nasal congestion

headache

cough

stuffy nose

minor aches and pains

sore throat

sinus congestion and pressure

- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

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.

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 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 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 (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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

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

Questions or comments? Call **1-877-290-4008**



MAXIMUM STRENGTH COLD AND FLU			
acetaminophen,dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-628
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	10 mg

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

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

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	78
Contains			

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 Drug	M012	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)

