

**MAXIMUM STRENGTH DAY COLD AND FLU FORMULA- acetaminophen,  
dextromethorphan, phenylephrine hcl capsule, liquid filled  
FAMILY DOLLAR**

*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.*

**632T FAMILY DOLLAR DAY MAX STRENGTH COLD AND FLU 55319-933-22**

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Inactive ingredients FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

**Purposes**

- Pain reliever/fever reducer
- Cough suppressant
- Nasal decongestant

**Uses**

- temporarily relieves these symptoms due to a cold or flu:
- minor aches and pains · headache · cough
- sore throat · nasal and sinus congestion
- temporarily reduces fever

**Directions:** · do not take more than the recommended dose

· adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 capsules in 24 hours or as

directed by a doctor.

· children under 12 years: do not use

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away(1800 222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Warnings**

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

- skin reddening · blisters · rash · hives
- facial swelling · asthma (wheezing) · shock

If a skin or general allergic 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.



Print/Varnish Omit Area

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acetaminophen, dextromethorphan, phenylephrine hcl capsule, liquid filled

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55319-933 |
| <b>Route of Administration</b> | 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 |
|---|----------|
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |
| POVIDONE (UNII: FZ989GH94E)                         |          |
| SHELLAC (UNII: 46N107B71O)                          |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                 |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                 |          |
| SORBITOL (UNII: 506T60A25R)                         |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)                  |          |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)                |          |
| GELATIN (UNII: 2G86QN327L)                          |          |
| GLYCERIN (UNII: PDC6A3C0OX)                         |          |
| WATER (UNII: 059QF0K00R)                            |          |

### Product Characteristics

|                 |        |                     |          |
|-----------------|--------|---------------------|----------|
| <b>Color</b>    | orange | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL   | <b>Size</b>         | 16mm     |
| <b>Flavor</b>   |        | <b>Imprint Code</b> | 70       |
| <b>Contains</b> |        |                     |          |

### Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55319-933-22 | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | 08/05/2020           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341                                  | 08/05/2020           |                    |

**Labeler** - FAMILY DOLLAR (024472631)

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

**Establishment**

| <b>Name</b>         | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|---------------------|----------------|---------------|----------------------------|
| MARKSANS PHARMA LTD |                | 925822975     | manufacture(55319-933)     |

Revised: 8/2020

FAMILY DOLLAR