MAXIMUM STRENGHT 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

 \cdot adults and children 12 years and over: take 2 sofgels 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

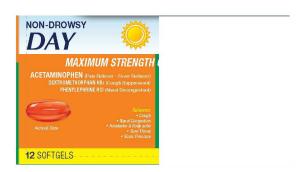
- · more than 4,000 mg of acetaminophen in 24 hours
- · with other drugs containing acetaminophen
- · 3 or more alcoholic drinks every day while using this product

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.



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acetaminophen, dextromethorphan, phenylephrine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-933
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients				
Ingredient Name	Strength			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PO VIDO NE (UNII: FZ989 GH9 4E)				
SHELLAC (UNII: 46 N10 7B710)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
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: 059QF0KO0R)				

Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	16 mm	
Flavor		Imprint Code	70	
Contains				

l	Packaging				
l	#	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				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LTD		925822975	manufacture (55319-933)	

Revised: 8/2020 FAMILY DOLLAR