# DAYTIME- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

H-E-B

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## 693T HEB 37808-093 Daytime Cold & Flu Softgels 16 count

#### **DRUG FACTS**

### Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylphrine HCl 5 mg

### **Purpose**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

**Uses** temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever

## Warnings

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

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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, lasts 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
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

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

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough get 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.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

#### **Directions**

- take only as directed
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over: 2 softgels with water every 4 hrs

children 4 to under 12 yrs: ask a doctor

children under 4 yrs: do not use

#### Other information

• store at room temperature

*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.

#### Questions?Call 1-877-290-4008



#### **DAYTIME**

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-093
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SORBITOL SOLUTION (UNII: 8KW3E207O2)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SORBITAN (UNII: 6092ICV9RU)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
GELATIN (UNII: 2G86QN327L)		
SHELLAC (UNII: 46N107B710)		
POVIDONE (UNII: FZ 989GH94E)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL (Oblong shaped)	Size	21mm
Flavor		Imprint Code	70
Contains			

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:37808-093- 16	2 in 1 CARTON	06/20/2022		
3		8 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/20/2022	

# **Labeler -** H-E-B (007924756)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	manufacture(37808-093)	

Revised: 2/2025 H-E-B