

**DAYTIME NIGHTTIME- acetaminophen, dextromethorphan hbr, phenylephrine hcl and acetaminophen, dextromethorphan hbr, doxylamine succinate H-E-B**

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**695T HEB 37808-191 Daytime Nighttime Cold & Flu Softgels Combo 48 count**

**DRUG FACTS - Daytime Cold & Flu**

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

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine 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 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, 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, chronic bronchitis, 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 right away (1-800-222-1222). 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 12yrs & 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**

#### ***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**

### **DRUG FACTS - Nighttime Cold & Flu**

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

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

#### ***Purpose***

Pain reliever/fever reducer

Cough suppressant

Antihistamine

#### ***Uses***

temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever
- runny nose & sneezing

#### ***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 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, 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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

**Ask a doctor or pharmacist before use if you are**

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

**When using this product**

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, & tranquilizers may increase drowsiness

**Stop use and ask a doctor if**

- pain, 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 breastfeeding,** 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 6 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 blue #1, D&C yellow #10, gelatin, glycerin, polyethylene

glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide.

Questions? Call 1-877-290-4008

Varnish Omit Area

Print/Varnish Omit Area

Compare to Vicks® DayQuil® & NyQuil® Cold & Flu active ingredients\*

Varnish Omit Area

**H-E-B**

## Daytime

**Acetaminophen**  
Pain Reliever/Fever Reducer  
Dextromethorphan HBr/Cough Suppressant  
Phenylephrine HCl/Nasal Decongestant

Cold & Flu

Relieves:

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Nasal Congestion, Sinus Pressure
- Cough

ACTUAL SIZE

32 SOFTGELS

NDC 37908-101-48

## Nighttime

**Acetaminophen**  
Pain Reliever/Fever Reducer  
Dextromethorphan HBr/Cough Suppressant  
Doxylamine Succinate/Antihistamine

Cold & Flu

Relieves:

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Sneezing, Runny Nose
- Cough

ACTUAL SIZE

16 SOFTGELS

48 TOTAL SOFTGELS

READ AND KEEP CAUTION FOR CONTAINER WARNINGS AND/OR IRRITATION. BLISTER UNIT IS OPEN OR TORN.

SAFETY SEAL: DO NOT USE IF THE INDIVIDUAL BLISTER UNIT IS OPEN OR TORN.

Drug Facts	Daytime Cold & Flu	Drug Facts	Nighttime Cold & Flu
<b>Active ingredients (in each softgel)</b>	<b>Purpose</b>	<b>Active ingredients (in each softgel)</b>	<b>Purpose</b>
Acetaminophen 325 mg	Pain reliever/fever reducer	Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant	Dextromethorphan HBr 15 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant	Doxylamine succinate 6.25 mg	Sleep aid
<b>Uses:</b> Temporarily relieves common cold/flu symptoms: • nasal congestion • cough due to upper/lower respiratory tract irritation • sore throat • headache • minor aches & pains • fever			
<b>Warnings:</b> Use carefully. 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, or with other drugs containing acetaminophen. • 3 or more alcoholic drinks every day while using this product.			
<b>Allergy Alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: • skin rash/itch • blisters • hives. If a skin reaction occurs, stop use and seek medical help right away.			
<b>See a doctor if:</b> If used for fever, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, vomiting, diarrhea.			

PARENTS: This product is not manufactured or distributed by Varnish Omit. Varnish Omit is a registered trademark of Vicks, Inc. ©2017.

Drug Facts (continued)

**Do not use:** • with any other drug containing acetaminophen (prescription or over-the-counter). If you take or plan to take a drug containing acetaminophen, ask a doctor or pharmacist. • if you are now taking a prescription medicine which is a blood thinner (warfarin) or a blood thinner (aspirin, ibuprofen, or other non-steroidal anti-inflammatory drugs) or for 2 weeks after stopping the blood thinner if you are now taking a prescription drug which is a blood thinner, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have:** • liver disease • kidney disease • high blood pressure • heart disease • alcoholism • trouble swallowing due to esophageal problems • cough that occurs with too much phlegm (mucus) • persistent or chronic cough or asthma with wheezing, asthma, or emphysema.

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.**

**When using this product, it is not safe to:** • drink alcohol.

**Do not use if you have:** • eye pain, redness, discharge, or tearing • pain, redness, or swelling of the mouth or throat • a fever that lasts more than 7 days • a fever that comes or goes more than 3 days • a fever or swelling in the breast • new symptoms occur • a cough comes back • a cough with red or bloody sputum.

**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. Check medical condition for infants & for children even if you do not notice any signs or symptoms.

<b>Directions:</b> • 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	

Drug Facts (continued)

**Do not use:** • with any other drug containing acetaminophen (prescription or over-the-counter). If you take or plan to take a drug containing acetaminophen, ask a doctor or pharmacist. • if you are now taking a prescription medicine which is a blood thinner (warfarin) or a blood thinner (aspirin, ibuprofen, or other non-steroidal anti-inflammatory drugs) or for 2 weeks after stopping the blood thinner if you are now taking a prescription drug which is a blood thinner, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have:** • liver disease • kidney disease • high blood pressure • heart disease • alcoholism • trouble swallowing due to esophageal problems • cough that occurs with too much phlegm (mucus) • persistent or chronic cough or asthma with wheezing, asthma, or emphysema.

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.**

**When using this product, it is not safe to:** • drink alcohol.

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**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. Check medical condition for infants & for children even if you do not notice any signs or symptoms.

<b>Directions:</b> • take only as directed • do not exceed 4 doses per 24 hrs	adults & children 12 yrs & over	2 softgels with water every 6 hrs
children 4 to under 12 yrs	ask a doctor	
children under 4 yrs	do not use	

Drug Facts (continued)

**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

MADE WITH PRIDE & CARE FOR H-E-B®  
1444 WESTWIND, TX 75248  
MADE IN INDIA

H-E-B

If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.

Drug Facts (continued)

**Other information:** • store at room temperature

**Inactive ingredients:** FD&C Blue #1, 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

5972-226

0 41220 96440 0

Lot #: Exp. Date:

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## DAYTIME NIGHTTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl and acetaminophen, dextromethorphan hbr, doxylamine succinate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37808-191
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-191-48	4 in 1 CARTON	06/20/2022	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	32
Part 2	4 BLISTER PACK	16

## Part 1 of 2

### DAYTIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

### Product Information

<b>Item Code (Source)</b>	NDC:37808-093
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL (Oblong shaped)	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	70
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	

## Part 2 of 2

### NIGHTIME

acetaminophen dextromethorphan hbr doxylamine succinate capsule, liquid filled

### Product Information

<b>Item Code (Source)</b>	NDC:37808-095
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL (Oblong shaped)	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	71
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 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	

### 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**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
MARKSANS PHARMA LIMITED		925822975	manufacture(37808-191)

Revised: 1/2023

H-E-B