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

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 righl 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 prostrate 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.

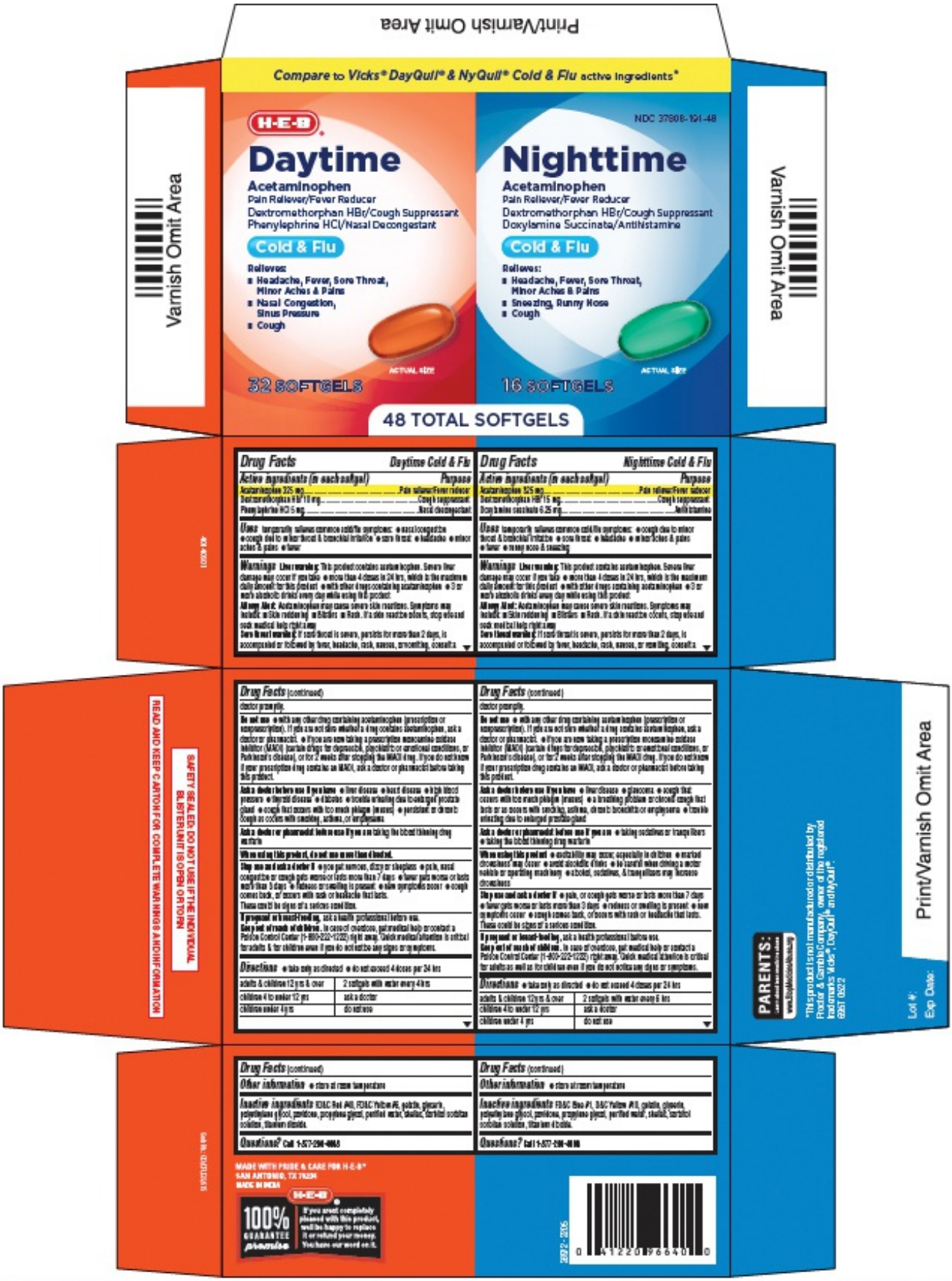
Directions
• take only as directed
• do not exceed 4 doses per 24 hrs
adults & children 12 yrs & over: 2 softgels with water every 6 hrs
children 4 to under 12 yrs: ask a doctor
children under 4 yrs: do not use

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**



DAYTIME NIGHTTIME

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37808-191

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	
Item Code (Source)	NDC:37808-093
Route of Administration	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**
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SHELLAC (UNII: 46N107B71O)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

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

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

Item Code (Source)	NDC:37808-095
Route of Administration	ORAL

Active Ingredient/Active Moiety

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

ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN (UNII: 6O92ICV9RU)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL (Oblong shaped)	**Size**	21mm
Flavor		**Imprint Code**	71
Contains			

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

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

Revised: 1/2023 H-E-B