

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

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.

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*

NDC 37808-101-48

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

32 SOFTGELS

Nighttime

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

Cold & Flu

Relieves:

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

16 SOFTGELS

48 TOTAL SOFTGELS

Varnish Omit Area

Drug Facts

Active ingredients (in each softgel)

Active ingredients (in each softgel)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses: Temporarily relieves common cold/flu symptoms: • nasal congestion • cough due to throat/bronchial irritation • sore throat • headache • minor aches & pains • fever

Warnings: 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 dose for this product, or with other drugs containing acetaminophen. • 3 or more alcoholic drinks every day while using this product.

Allergy Alert: Acetaminophen may cause severe skin reactions. Symptoms may include: • skin redness/itching • blisters • rash. If a skin reaction occurs, stop taking your medicine, help right away.

See a doctor now if: If cold/flu is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or sore throat, sore throat.

Drug Facts

Active ingredients (in each softgel)

Active ingredients (in each softgel)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Sleeping aid

Uses: Temporarily relieves common cold/flu symptoms: • cough due to throat/bronchial irritation • sore throat • headache • minor aches & pains • fever • runny nose & sneezing

Warnings: 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 dose for this product, or with other drugs containing acetaminophen. • 3 or more alcoholic drinks every day while using this product.

Allergy Alert: Acetaminophen may cause severe skin reactions. Symptoms may include: • skin redness/itching • blisters • rash. If a skin reaction occurs, stop taking your medicine, help right away.

See a doctor now if: If cold/flu is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or runny nose, sore throat.

Drug Facts (continued)

Other information: • Store at room temperature.

Inactive ingredients: FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, polyethylene glycol, purified water, shellac, sorbitol, sodium lauryl sulfate, titanium dioxide.

Questions? Call 1-877-234-4663

MADE WITH PRIDE & CARE FOR H-E-B®
SAN ANTONIO, TX 78204
MADE IN INDIA

100% GUARANTEE
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, polyethylene glycol, purified water, shellac, sorbitol, sodium lauryl sulfate, titanium dioxide.

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Other information: • Store at room temperature.

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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
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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

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: 3WJQ0SDW1A)	
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)	

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 final	part341	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: 3WJQ0SDW1A)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN (UNII: 6O92ICV9RU)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6A3C0OX)	

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 final	part341	06/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	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)

