

DAYTIME NIGHTTIME ULTRA CONCENTRATED- daytime - acetaminophen, dextromethorphan hbr, phenylephrine hcl and nighttime - acetaminophen, dextromethorphan hbr, doxylamine succinate
CVS HEALTH CORP

CVS 778T Daytime Nighttime Ultra Concentrated Cold and Flu Softgels

Drug Facts

Daytime Ultra Concentrated Cold & Flu

Active ingredient (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 8 softgels in 24 hours, which is the maximum daily amount for this product
- 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 reddening
- blisters
- rash

If a skin 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.

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 such 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 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 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 as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed
- do not exceed 8 softgels 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 no greater than 25°C

Inactive ingredients

FD&C yellow no. 6 Al. lake, gelatin, glycerin, mica, polyethylene glycol 400, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

Call **1-877-290-4008**

Drug Facts

Nighttime Ultra Concentrated Cold & Flu

Active ingredient (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 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 8 softgels in 24 hours, which is the maximum daily amount for this product
- 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 reddening
- blisters
- rash

If a skin 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.

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

- **do not use more than directed**
- 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, and 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 breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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Directions

- take only as directed
- do not exceed 8 softgels 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 no greater than 25°C

Inactive ingredients

D&C yellow no. 10 Al. lake, FD&C blue no. 1 Al. lake, gelatin, glycerin, mica, polyethylene glycol 400, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

Call **1-877-290-4008**

778T carton

Varnish Omit Area

Nighttime Ultra Concentrated Cold & Flu	Daytime Ultra Concentrated Cold & Flu
<p>Drug Facts</p> <p>Active ingredients (in each softgel)</p> <ul style="list-style-type: none"> Acetaminophen 325 mg Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg <p>Purpose</p> <ul style="list-style-type: none"> Pain reliever/fever reducer Cough suppressant Antihistamine <p>Uses temporarily relieves common cold/flu symptoms:</p> <ul style="list-style-type: none"> cough due to minor throat & bronchial irritation runny nose headache minor aches & pains fever <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 softgels in 24 hours, which is the maximum daily amount for this product.</p> <p>Do not use with other drugs containing acetaminophen.</p> <p>Do not use if you are 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.</p> <p>Other information store at no greater than 25°C</p> <p>Questions or comments? Call 1-877-299-4008</p>	<p>Drug Facts</p> <p>Active ingredients (in each softgel)</p> <ul style="list-style-type: none"> Acetaminophen 325 mg Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg <p>Purpose</p> <ul style="list-style-type: none"> Pain reliever/fever reducer Cough suppressant Antihistamine <p>Uses temporarily relieves common cold/flu symptoms:</p> <ul style="list-style-type: none"> head congestion cough due to minor throat & bronchial irritation runny nose headache minor aches & pains fever <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 softgels in 24 hours, which is the maximum daily amount for this product.</p> <p>Do not use with other drugs containing acetaminophen.</p> <p>Do not use if you are 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.</p> <p>Other information store at no greater than 25°C</p> <p>Questions or comments? Call 1-877-299-4008</p>

Ultra Concentrated DAYTIME COLD & FLU

48 DAYTIME SOFTGELS

Ultra Concentrated NIGHTTIME COLD & FLU

48 NIGHTTIME SOFTGELS

MAXIMUM STRENGTH COMBO PACK

Ultra Concentrated DAYTIME COLD & FLU

Acetaminophen, 325 mg Pain Reliever, Fever Reducer

Dextromethorphan HBr, 10 mg Cough Suppressant

Phenylephrine HCl, 5 mg Nasal Decongestant

Ultra Concentrated NIGHTTIME COLD & FLU

Acetaminophen, 325 mg Pain Reliever, Fever Reducer

Dextromethorphan HBr, 10 mg Cough Suppressant

Doxylamine Succinate, 6.25 mg Antihistamine

Compare to Vicks® DayQuil® & NyQuil® Ultra Concentrated Cold & Flu LiquiCaps™ active ingredients*

Multi-Symptom Relief: Headache, Fever, Sore Throat, Minor aches & pains, Cough, Nasal congestion, Sinus pressure

Multi-Symptom Relief: Headache, Fever, Sore Throat, Minor aches & pains, Cough, Sneezing, Runny nose - Nighttime Relief

48 DAYTIME SOFTGELS 48 NIGHTTIME SOFTGELS

Easy To Swallow 96 TOTAL SOFTGELS *Under OTC monograph.

LOT: EXP: Print/Varnish Omit Area

778T Daytime label

NDC 51316-873-78

Ultra Concentrated DAYTIME COLD & FLU

Acetaminophen, 325 mg

Pain Reliever, Fever Reducer

Dextromethorphan HBr, 10 mg, Cough Suppressant

Phenylephrine HCl, 5 mg, Nasal Decongestant

48 SOFTGELS

RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

TAMPER EVIDENT: DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

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 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 8 softgels in 24 hours, which is the maximum daily amount for this product.

Do not use with other drugs containing acetaminophen.

Do not use if you are 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.

Other information store at no greater than 25°C

Questions or comments? Call 1-877-299-4008

LOT: EXP: Print/Varnish Omit Area

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NOT FOR RESALE

PEEL HERE FOR DRUG FACTS

RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

TAMPER EVIDENT: DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts (continued)

more than 8 softgels in 24 hours, which is the maximum daily amount for this product

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, hives, rash

If a skin 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.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

Directions

take only as directed

do not exceed 8 softgels 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

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778T Nighttime label

NDC 51316-874-78

Ultra Concentrated NIGHTTIME COLD & FLU

Acetaminophen, 325 mg

Pain Reliever, Fever Reducer

Dextromethorphan HBr, 10 mg, Cough Suppressant

Doxylamine Succinate, 6.25 mg, Antihistamine

48 SOFTGELS

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Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	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

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TAMPER EVIDENT: DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

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LOT: EXP: Print/Varnish Omit Area

DAYTIME NIGHTTIME ULTRA CONCENTRATED

daytime - acetaminophen, dextromethorphan hbr, phenylephrine hcl and nighttime -

acetaminophen, dextromethorphan hbr, doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-875
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-875-83	1 in 1 CARTON	04/01/2026	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	48
Part 2	1 BOTTLE	48

Part 1 of 2

DAYTIME ULTRA CONCENTRATED COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Item Code (Source)	NDC:51316-873
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
SORBITAN (UNII: 6O92ICV9RU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
MICA (UNII: V8A1AW0880)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	151
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		48 in 1 BOTTLE; 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	04/01/2026	

Part 2 of 2

NIGHTTIME ULTRA CONCENTRATED COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Item Code (Source)	NDC:51316-874
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
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SHELLAC (UNII: 46N107B71O)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)
SORBITOL (UNII: 506T60A25R)
MICA (UNII: V8A1AW0880)
GLYCERIN (UNII: PDC6A3C0OX)
WATER (UNII: 059QF0KO0R)
SORBITAN (UNII: 6O92ICV9RU)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POVIDONE (UNII: FZ989GH94E)
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)
GELATIN (UNII: 2G86QN327L)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	152
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		48 in 1 BOTTLE; 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	04/01/2026	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/01/2026	

Labeler - CVS HEALTH CORP (062312574)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment			
Name	Address	ID/FEI	Business Operations

MARKSANS PHARMA LIMITED

925822975

manufacture(51316-875)

Revised: 3/2026

CVS HEALTH CORP