ULTRA CONCENTRATED DAYTIME/ NIGHTTIME SEVERE SOFTGEL- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride softgel
CVS PHARMACY, INC

CVS 647T Ultraconcentratd Daytime & Nighttime severe cold & flu softgels

Daytime Cold & Flu - Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:

- minor aches and pains

- headache

- nasal congestion

- sore throat

- sinus congestion and pressure

- cough

- temporarily reduces fever

Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- hives

- facial swelling
- asthma (wheezing)
- shock

If a skin or general allergic 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.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough with excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- 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 exceed recommended dosage

Stop use and ask a doctor if

- pain, cough, or nasal congestion 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.
- nervousness, dizziness, or sleeplessness occurs

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

- do not take more than the recommended dose
- do not take the Day and Night products at the same time; wait 4 hours after the last Night dose before starting Day product.
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 6 softgels with water every 4 hours. Do not exceed 6 softgels in 12 hours or as directed by a doctor.
- children under 12 years: 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**

Nighttime Severe Cold & flu - Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:

- minor aches and pains
- headache
- nasal congestion
- cough
- sinus congestion and pressure
- runny nose
- sneezing
- sore throat

- temporarily reduces fever

Warnings

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

you take
- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:
- skin reddening
- blisters
- rash
- hives
- facial swelling
- asthma (wheezing)
- shock

If a skin or general allergic 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 to sedate children.

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.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if you have
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- 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
- taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- pain, cough, or nasal congestion 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.
- nervousness, dizziness, or sleeplessness occurs

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

- do not take more than the recommended dose
- do not take the Day and Night products at the same time; wait 4 hours after the last Day dose before starting Night product.
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 4 softgels in 12 hours or as directed by a doctor.
- children under 12 years: 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, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or comments? Call **1-877-290-4008**

Front of Package

NDC XXXXX-XXX-XX

MAXIMUM STRENGTH

†Compare to the active ingredients in Alka-Seltzer Plus® Cold & Flu Maximum Strength Day & Night PowerMax® Gels

Daytime Ultra Concentrated Cold & Flu

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

- Nasal Congestion
- Sore Throat
- Headache & Body Ache
- Sinus Pressure
- Cough

Actual Size
16 Daytime Softgels

16 SOFTGELS
24 TOTAL SOFTGELS

Nighttime Severe Ultra Concentrated Cold & Flu

Acetaminophen
(Pain Reliever / Fever Reducer)
Dextromethorphan HBr
(Cough Suppressant)
Doxylamine Succinate
(Antihistamine)
Phenylephrine HCl
(Nasal decongestant)

- Nasal Congestion
- Runny Nose
- Headache & Body Ache
- Cough
- Sore Throat

Actual Size
8 Nighttime Softgels

8 SOFTGELS

ULTRA CONCENTRATED DAYTIME/ NIGHTTIME SEVERE SOFTGEL

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride softgel kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51316-547

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51316-547-24	2 in 1 CARTON	02/01/2025	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	2 BLISTER PACK	16 in 2
Part 2	2 BLISTER PACK	8 in 2

Part 1 of 2

DAYTIME ULTRA CONCENTRATED

acetaminophen, dextromethorphan hbr, phenylephrine hcl softgel capsule

Product Information	
Item Code (Source)	NDC:51316-577
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**
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN (UNII: 6O92ICV9RU)	
MICA (UNII: V8A1AW0880)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	151
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	02/01/2025	

Part 2 of 2

NIGHTTIME SEVERE ULTRA CONCENTRATED

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl softgel capsule

Product Information	
Item Code (Source)	NDC:51316-446
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SORBITAN (UNII: 6O92ICV9RU)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICA (UNII: V8A1AW0880)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	163
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	02/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/01/2025	

Labeler - CVS PHARMACY, INC (062312574)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations

MARKSANS PHARMA LIMITED		925822975	manufacture(51316-547)