# OVERNIGHT COLD AND FLU- acetaminophen, dextromethorphan hbr, triprolidine hcl solution WALGREENS CO

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.

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#### Overnight Cold & Flu

#### **Drug Facts**

Active ingredients (in each 20 mL)	Purposes
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Triprolidine HCl 2.5 mg	Antihistamine

#### Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - runny nose
  - sneezing
  - sinus congestion and pressure
  - itching of the nose or throat
  - itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

#### **Warnings**

#### Liver warning

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

- more than 4000 mg in 24 hours, which is the maximum daily amount
- 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, 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
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

#### 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 use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

#### 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 fever, 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.

#### Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. 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 directed (see Overdose warning)
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- adults and children 12 years of age and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

#### Other information

- each 20 mL contains: sodium 10 mg
- low sodium
- store at room temperature
- do not refrigerate

#### **Inactive ingredients**

anhydrous citric acid, ascorbic acid, edetate disodium, FD&C Blue No. 1, FD&C Red No. 10, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol citrate, sorbitol, sucralose, xanthan gum

#### Questions or comments?

1-866-467-2748

#### Principal Display Panel - 180 mL Bottle Label

NDC 0363-6980-06

Overnight Cold & Flu

**Acetaminophen** – Pain Reliever/Fever Reducer Dextromethorphan HBr – Cough Suppressant Triprolidine HCl – Antihistamine

### NIGHT TIME

#### Relief for a Better Morning

- Cough
- Fever

- Sore throat
- Runny nose
- Sneezing

#### 6 FL OZ (180 mL)For Ages 12+

#### Tamper evident: do not use if printed seal under cap is broken or missing

Maximum Strength per 4-hour dose

\*This product is not manufactured or distributed by RB Health, the distributor of Mucinex® Nightshift Cold & Flu.









MINUTE LAYER FACE ALL



#### **OVERNIGHT COLD AND FLU**

acetaminophen, dextromethorphan hbr, triprolidine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-6980
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	650 mg in 20 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL	
<b>TRIPRO LIDINE HYDRO CHLO RIDE</b> (UNII: YAN7R5L890) (TRIPRO LIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 20 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
ASCORBIC ACID (UNII: PQ6CK8PD0R)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYL GALLATE (UNII: 8 D4S NN7 V92)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SO DIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		

	Packaging			
	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
	1 NDC:0363-6980-06	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/28/2020	
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Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/28/2020	

## Labeler - WALGREENS CO (008965063)

Revised: 2/2020 WALGREENS CO