

UP AND UP COLD FLU RELIEF DAY NIGHT- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl

Target Corporation

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.

Target Corporation Cold/Flu Relief Day Night Drug Facts

Active ingredients - Nighttime (in each 30 mL dose cup)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Active ingredients - Daytime (in each 15 mL tablespoon)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose - Nighttime

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Purpose - Daytime

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses - Nighttime

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

Uses - Daytime

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

Warnings - Nighttime

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 4 doses (2,600 mg acetaminophen) in 24 hours. 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

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Warnings - Daytime

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 4 doses (adult: 2,600 mg acetaminophen; child: 1,300 mg acetaminophen) in 24 hours. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use - Nighttime

- 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.
- to make a child sleepy
- if you have ever had an allergic reaction to this product or any of its ingredients

Do not use - Daytime

- 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

Ask a doctor before use if you have - Nighttime

- liver disease
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- a sodium-restricted diet

Ask a doctor before use if you have - Daytime

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are - Nighttime

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

Ask a doctor or pharmacist before use if you are - Daytime

taking the blood thinning drug warfarin

When using this product - Nighttime

- 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

When using this product - Daytime

do not use more than directed

Stop use and ask a doctor if - Nighttime

- 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.

Stop use and ask a doctor if - Daytime

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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 - Nighttime

- take only as directed – see Liver warning
- use dose cup
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL (2 TBSP) every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Directions - Daytime

- take only as directed – see Liver warning
- use dose cup
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL (2 TBSP) every 4 hrs
children 6 to under 12 yrs	15 mL (1 TBSP) every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information - Nighttime

- each 30 mL dose cup contains: sodium 39 mg
- store at 20-25°C (68-77°F)

Other information - Daytime

- each tablespoon contains: sodium 7 mg
- store at 20-25°C (68-77°F)

Inactive ingredients - Nighttime

alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Inactive Ingredients - Daytime

butylated hydroxyanisole, edetate disodium, FD&C yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

Questions?

Call 1-800-910-6874

Principal Display Panel - Daytime

Compare to active ingredients in Vicks® DayQuil® Cold & Flu

cold/flu relief

multi-symptom

day / non-drowsy

pain reliever/fever reducer, cough suppressant, nasal decongestant

acetaminophen – aches/fever

dextromethorphan HBr – cough

phenylephrine HCl – nasal congestion

alcohol free, antihistamine free

DAY

original flavor

Principal Display Panel - Nighttime

Compare to active ingredients in Vicks® NyQuil® Cold & Flu

cold/flu relief

multi-symptom

night

antihistamine, cough suppressant, fever reducer/pain reliever

acetaminophen – aches/fever/sore throat

dextromethorphan HBr – cough

doxylamine succinate – sneezing, runny nose

does not contain pseudoephedrine

ALCOHOL 10%

NIGHT

cherry flavor

TWO – 12 FL OZ (355 mL), TOTAL 24 FL OZ (1.5 pt) (710 mL)

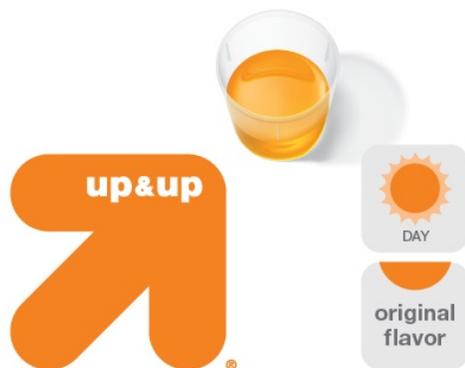
DO NOT USE IF PRINTED NECKBAND
IS BROKEN OR MISSING

Compare to active ingredients in
Vicks® DayQuil® Cold & Flu*

cold/flu relief multi-symptom day/non-drowsy

pain reliever/fever reducer, cough
suppressant, nasal decongestant

acetaminophen – aches/fever
dextromethorphan HBr – cough
phenylephrine HCl – nasal congestion
alcohol free, antihistamine free



TWO – 12 FL OZ (355 mL), TO

NDC 11673-733-02

Compare to active ingredients in
Vicks® NyQuil® Cold & Flu*

cold/flu relief multi-symptom night

antihistamine, cough suppressant,
fever reducer/pain reliever

acetaminophen – aches/fever/sore throat
dextromethorphan HBr – cough
doxylamine succinate –
sneezing/runny nose
does not contain pseudoephedrine
ALCOHOL 10%



AL – 24 FL OZ (1.5 pt)(710 mL)

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*These products are not manufactured or distributed by Procter & Gamble,
distributor of Vicks® DayQuil® Cold & Flu and Vicks® NyQuil® Cold & Flu.

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

Drug Facts (continued)

Other information ■ each 30 mL dose cup contains: sodium 39 mg
■ store at 20-25°C (68-77°F)

Inactive ingredients alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions? Call 1-800-910-6874

Drug Facts

Nighttime Cold & Flu

Active ingredients (in each 30 mL dose cup)

Acetaminophen 650 mg.....Pain reliever/fever reducer
Dextromethorphan HBr 30 mg.....Cough suppressant
Doxylamine succinate 12.5 mg.....Antihistamine

Uses temporarily relieves common cold/flu symptoms: ■ headache
■ cough due to minor throat and bronchial irritation ■ sore throat
■ minor aches and pains ■ runny nose and sneezing ■ fever

Purpose

Drug Facts (continued)

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 4 doses (2,600 mg acetaminophen) in 24 hours. 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

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is 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. ■ to make a child sleepy ■ if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have ■ liver disease ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ a sodium-restricted diet

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, 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. 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 - see Liver warning

■ use dose cup ■ do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL (2 TBSP) every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

■ when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Drug Facts**Daytime Cold & Flu****Active ingredients (in each 15 mL tablespoon)**

Acetaminophen 325 mg.....	Pain reliever/fever reducer	Purpose
Dextromethorphan HBr 10 mg.....	Cough suppressant	
Phenylephrine HCl 5 mg.....	Nasal decongestant	

Uses temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- headache
- minor aches and pains
- fever
- sore throat
- nasal congestion

Drug Facts (continued)**Other information** ■ each tablespoon contains: sodium 7 mg

- store at 20-25°C (68-77°F)

Inactive ingredients butylated hydroxyanisole, edetate disodium, FD&C

yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

Questions? Call 1-800-910-6874**Drug Facts (continued)****Warnings**

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 4 doses (adult: 2,600 mg acetaminophen; child: 1,300 mg acetaminophen) in 24 hours. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount

■ taken with other drugs containing acetaminophen
 ■ adult has 3 or more alcoholic drinks every day while using this product

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is 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

Ask a doctor before use if you have ■ liver disease ■ high blood pressure ■ heart disease ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough 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 ■ pain, nasal congestion or cough gets worse or lasts more than 5 days (children) or 7 days (adults) ■ you get nervous, dizzy or sleepless ■ 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.

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Directions ■ take only as directed - see Liver warning

- use dose cup
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adults & children 12 yrs & over	30 mL (2 TBSP) every 4 hrs
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children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

■ when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

UP AND UP COLD FLU RELIEF DAY NIGHT

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:11673-733

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-733-02	1 in 1 CARTON; Type 0: Not a Combination Product	08/18/2014	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	355 mL
Part 2	1 BOTTLE	355 mL

Part 1 of 2

UP AND UP COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate suspension

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	RED (Clear/Dark Red)	Score	
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Shape		Size	
Flavor	CHERRY (Menthol Aroma)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		355 mL 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 final	part341	09/22/2011	

Part 2 of 2

UP AND UP COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl suspension

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	

XANTHAN GUM (UNII: TTV12P4NEE)	
MENTHOL (UNII: L7T10EIP3A)	

Product Characteristics			
Color	ORANGE (clear)	Score	
Shape		Size	
Flavor	MENTHOL (with fruit)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		355 mL 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 final	part341	07/07/2009	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/18/2014	

Labeler - Target Corporation (006961700)