

UP AND UP DAYTIME NIGHTTIME COLD AND FLU- 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 Daytime Nighttime Cold and Flu Drug Facts

Nighttime Cold & Flu

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

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

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 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.
- 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.

Overdose warning: 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 Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

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

Other information

- each 30 mL 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 1-888-547-7400

Daytime Cold & Flu

Active ingredients (in each 15 mL)

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 and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

Warnings

Liver warning: This product contains acetaminophen. 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
- taken with other drugs containing acetaminophen
- adult has 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.
- 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
- 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 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 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.

Overdose warning: 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 Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

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

Other information

- each 15 mL 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 1-888-547-7400

Package/Label Principal Display Panel

see new warnings

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

daytime cold and flu

multi-symptom relief

acetaminophen (pain reliever/fever reducer)

dextromethorphan HBr (cough suppressant)

phenylephrine HCl (nasal decongestant)

aches, fever, sore throat

nasal congestion and cough

non-drowsy/alcohol free/antihistamine free

12 FL OZ (355 mL)

see new warnings

Compare to active ingredients in Vicks NyQuil® Cold & Flu

value pack

nighttime cold and flu

nighttime relief

acetaminophen (pain reliever/fever reducer)

dextromethorphan HBr (cough suppressant)

doxylamine succinate (antihistamine)

aches, fever, sore throat

sneezing, runny nose, cough

ALCOHOL 10%

CHERRY FLAVOR

12 FL OZ (355 mL)

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

**DO NOT USE IF PRINTED
NECKBAND IS
BROKEN OR MISSING**

Drug Facts (continued)
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 1-888-547-7400

see new warnings

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

daytime cold and flu multi-symptom relief

acetaminophen
(pain reliever/fever reducer)
dextromethorphan HBr
(cough suppressant)
phenylephrine HCl
(nasal decongestant)

aches, fever, sore throat
nasal congestion and cough
non-drowsy/alcohol free/antihistamine free



12 FL OZ (355 mL)

see new warnings

NDC 11673-021-02

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

value
pack

nighttime cold and flu nighttime relief

acetaminophen
(pain reliever/fever reducer)
dextromethorphan HBr
(cough suppressant)
doxylamine succinate
(antihistamine)

aches, fever, sore throat
sneezing, runny nose, cough
ALCOHOL 10%



12 FL OZ (355 mL)



GLUTEN FREE

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Drug Facts (continued)
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 1-888-547-7400

Drug Facts	Nighttime Cold & Flu	Drug Facts	Daytime Cold & Flu
Active ingredients (in each 30 mL)	Purpose Acetaminophen 650 mg..... Pain reliever/fever reducer Dextromethorphan HBr 30 mg..... Cough suppressant Doxylamine succinate 125 mg..... Antihistamine	Active ingredients (in each 15 mL)	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: cough due to minor throat and bronchial irritation sore throat, headache, minor aches and pains, fever, runny nose and sneezing	Uses	Temporarily relieves common cold/flu symptoms: cough due to minor throat and bronchial irritation sore throat, headache, minor aches and pains, fever, nasal congestion
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 reactions. Symptoms may include: skin redness, 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. If you have ever had an allergic reaction to this product or any of its ingredients	Warnings	Liver warning: This product contains acetaminophen. 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 taken with other drugs containing acetaminophen adult has 3 or more alcoholic drinks every day while using this product Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, 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. 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, glaucoma, cough that occurs with too much phlegm (mucus), 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, a sodium-restricted diet	Ask a doctor before use if you have	liver disease, heart disease, thyroid disease, high blood pressure, trouble urinating due to an enlarged prostate gland, cough that occurs with too much phlegm (mucus), persistent or chronic cough such as occurs with smoking, asthma, or emphysema, diabetes
Ask a doctor or pharmacist before use if you are	taking sedative or tranquilizers, taking the blood thinning drug warfarin	Ask a doctor or pharmacist before use if you are	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	When using this product on those more than 16 years old	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.	Stop use and ask a doctor if	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	If pregnant or breast-feeding,	ask a health professional before use
Keep out of reach of children. Overdose warning:	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.	Keep out of reach of children. Overdose warning:	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 Overdose warning, only use the dose cup provided, do not exceed 4 doses per 24 hrs adults & children 12 yrs & over 30 mL every 4 hrs children 6 to under 12 yrs 15 mL every 4 hrs children 4 to under 6 yrs ask a doctor children under 4 yrs do not use	Directions	take only as directed—see Overdose warning, only use the dose cup provided, do not exceed 4 doses per 24 hrs adults & children 12 yrs & over 30 mL every 4 hrs children 6 to under 12 yrs 15 mL every 4 hrs children 4 to under 6 yrs ask a doctor children under 4 yrs do not use
Other information	each 30 mL contains: sodium 39 mg, store at 20-25°C (68-77°F)	Other information	each 15 mL contains: sodium 7 mg, store at 20-25°C (68-77°F)

UP AND UP DAYTIME NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-021
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-021-02	1 in 1 CARTON; Type 0: Not a Combination Product	03/13/2015	

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 NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

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	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	
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	03/10/2015	

Part 2 of 2

UP AND UP DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

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 (UNII: 3980JH2SW)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MENTHOL (UNII: L7T10EP3A)	

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	02/26/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/13/2015	

Labeler - Target Corporation (006961700)