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

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 & 30 mL (2 TBSP) every 6 hrs					
over					
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)



Drug Facts Nighttime Cold & Flu	Active ingredients (in each 30 mL dose cup) Purpose Acetaminophen 650 mg	Doxylamine succinate 12.5 mg	So -	dose of this product is 4 doses (2,60 Severe liver damage may occur if you acetaminophen in 24 hours with any or more alcoholic drinks every of the sore throat warning: If sore throat occurs with or is followed by fever, I consult a doctor promptly. Do not use with any other drug on nonprescription). If you are not sure wask a doctor or pharmacist if you oxidase inhibitor (MAOI) (certain drug conditions, or Parkinson's disease), or if you do not know if your prescription pharmacist before taking this product have ever had an allergic reaction to the due to an enlarged prostate gland phlegm (mucus) persistent or coasthma, or emphysema a breat chronic bronchitis glaucoma. Ask a doctor or pharmacist before	to take more than 4,000 mg of the other drugs containing acetaminophen day while using this product is severe, lasts for more than 2 days, needache, rash, nausea, or vomiting, containing acetaminophen (prescription or whether a drug contains acetaminophen, are now taking a prescription monoamine is for 2 weeks after stopping the MAOI drug, drug contains an MAOI, ask a doctor or to make a child sleepy if you this productor any of its ingredients to make a child sleepy if you this productor any of its ingredients to much thronic cough as occurs with too much thronic cough as occurs with smoking, thing problem such as emphysema or a sedium-restricted diet
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, purified water, saccharin sodium, sodium citrate Questions? Call 1-800-910-6874		Questions? Call 1-800-910-6874	When using this product ■ exci ■ marked drowsiness may occur ■ be careful when driving a motor v ■ alcohol, sedatives, and tranquilize Stop use and ask a doctor if ■ than 7 days ■ fever gets worse or swelling is present ■ new sympton with rash or headache that lasts. The lift pregnant or breast-feeding, ask Keep out of reach of children. In cor contact a Poison Control Center medical attention is critical for adult not notice any signs or symptoms. Directions ■ take only as direct use dose cup ■ do not exceed adults & children 12 yrs & over children 4 to under 12 yrs children under 4 yrs	ers may increase drowsiness pain or cough gets worse or lasts more lasts more than 3 days redness or as occur cough comes back or occurs ese could be signs of a serious condition. The area of overdose, get medical help light away. (1-800-222-1222) Quick ts as well as for children even if you do	

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. 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 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

label to insure correct dosing

Dextromethorphan HBr 10 mg..... Active ingredients (in each 15 mL tablespoon, *Facts*

cough due to minor throat and bronchial irritation **Uses** temporarily relieves common cold/flu symptoms: Pain reliever/tever reduce sore throat .Cougn suppressam

fever

nasal congestion

Questions? Call 1-800-910-6874

Daytime Cold & Flu

glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene ■ store at 20-25°C (68-77°F) Other information Inactive ingredients butylated hydroxyanisole, edetate disodium, FD&C each

tablespoon contains: sodium 7

mc

Drug Facts (continued)

■ when using other Daytime or Nighttime products, carefully read each

UP AND UP COLD FLU RELIEF DAY NIGHT

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

HUMAN OTC DRUG **Product Type** Item Code (Source)

NDC:59368-005

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59368-005- 01	1 in 1 CARTON; Type 0: Not a Combination Product	08/18/2014		

Quant	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: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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				

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	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 Drug	M012	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

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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: 3MJQ0SDWIA)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0K00R)

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 Drug	M012	07/07/2009	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/18/2014	

Labeler - Sixarp, LLC (016329513)

Establishment			
Name	Address	ID/FEI	Business Operations
Sixarp, LLC		016329513	manufacture(59368-005) , label(59368-005) , pack(59368-005)

Revised: 3/2024 Sixarp, LLC