# EQUATE NITETIME DAYTIME- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl Wal-Mart Stores Inc

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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#### Wal-Mart NiteTime DayTime 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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- 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 or comments?

1-888-287-1915

#### 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 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 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 15 mL contains: sodium 7 mg
- store at 20-25°C (68-77°F)

#### **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 or comments?

1-888-287-1915

#### **Principal Display Panel**

#### SEE NEW WARNINGS

Compare to DayQuil® Cold & Flu & NyQuil® Cold & Flu Active Ingredients Non-Drowsy DayTime Cold & Flu Pain Reliever, Fever Reducer, Cough Suppressant, Nasal Decongestant Multi-Symptom Relief Aches, fever – Acetaminophen Cough – Dextromethorphan HBr Nasal congestion – Phenylephrine HCl Alcohol Free and Antihistamine Free 12 FL OZ (355mL) SEE NEW WARNINGS Compare to DayQuil® Cold & Flu & NyQuil® Cold & Flu Active Ingredients NiteTime Cold & Flu Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine Multi-Symptom Relief Aches, fever – Acetaminophen Cough – Dextromethorphan HBr Sneezing, runny nose – Doxylamine Succinate 10% ALCOHOL 12 FL OZ (355mL)



Drug Facts Nighttime Cold & Flu	Drug Facts Daytime Cold & Flu			
Active ingredients (in each 30 mL)         Purpose           Acetaminop hen 650 mg         Pain reliever/fever reducer           Dextrometh orph an HBr 30 mg         Cough s uppressant           Doxylamine succh ate 12.5 mg         Anthistamine	Active ingredients (in each 15 mL) Purpose Acetaminophen 325 mg			
Uses temporarily refeves common cold/flu symptoms: Cough due to minor thinat and bronchial irritation screith inat Cheadache Cough and sins fever runny nose and sneezing	Uses ■ temporarily relieves common cold/fu symptoms: ■ cough due to minor throat and bronchial irritation ■ scre th pat ■ headache ■ minor aches and pains ■ fever ■ nasal congestion			
Warnings           Liver warning: This product contains acetaminophen. Severe liverdamage 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           All ergy alert Acetaminophen may cause severe skin readbins. Symptoms may include:           skin reddening         bitsits           skin reddening         bitsits           Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied orfolowed by fever, headache, rash, nausea, or vom ting, consult a doctor promptly.	Warnings           Liver warning:         This product contains acetaminophen. Severe liver damage may occur if           acultitakes more than 4.000 mg of acetaminophen in 24 hours         Ichours           child takes more than 5 doses in 24 hours         Itaken with other drugs containing acetaminophen           acultitakes more than 5 doses in 24 hours         Itaken with other drugs containing acetaminophen           acultitakes nore than 5 doses in 24 hours         Itaken with other drugs containing acetaminophen           acultitakes 3 or more alcoholic drinks every d ay while using this product         Allergy alert Acetaminophen may cause severe skin reacton occurs, stopuse and seekmedical heb right away.           Skin reddening         Iblistes         Trash If a skin reacton occurs, stopuse and seekmedical heb right away.           Sore thm at warning: If sore throat is severe, persists for more than 2 days, is accompanied orfolowed by fever, headache, rash, nause, ar vom ting, consult a doctor promptiv.			
Do notuse ■ with any other dug containing acetaminophen (prescriptionor nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ if you are now taking a prescription monoam he oxidase inhibitor (MAOI) (cartain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks afters bopping the MAOI drug. If you do not know if you prescription drug con tains 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	Do notuse with any other drug containing acetaminophen (prescriptionor 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) (cartain 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 you 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 in gradients.			
Ask a do ctor before use if you have liver disease glaucoma Ecough that cocurs with bo much phlegm (mucus) trouble u inating due to an enlarged prostate gland a breathing problem such as emphysema or chronic bronchils Dersistent or chronic cound has occurs with smoking, as stima, or emphysema as asodium-restricted diet	Ask a doc br be bre use if you have liver disease liker disease thryroid disease liker by book pressure trouble urhating due to an enlarged prostate gland licer by book with bo much phlegm (mucus) persistent or chronic cough such as occurs with smoking, asth ma, or emphysem a lidebets			
Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilzers ■ 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 do not usemore than directed			
When using this product excitability may occur, especially in children marked drow siness may occur avdid a looholic drinks be careful when driving a motor vehicle or operating machinery alcohol, sedatives, and tranquilizers may increase drow siness Stop use and ask a doctor if pain or cough gets worse or lasts more than 7 days	Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ pain, næal congestion or cough gets worse or lasts more than 5 days (ch idren) or 7 days (ad uits) ■ fevergets worse or lasts more than 3 days ■ redness or swellin gis pesent ■ new symptoms occur ■ cough comes backor occurs with rash or headache that lasts. These could be signs of a serious condition.			
■ fevergets worse or lasts more than 3 days ■ redness ors welling is present ■ new symptoms occur ■ cough comes back or occurs with rash or head ache 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 healthp ofessional before us e. Keep out of reach of children. O verdose 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			
Keep out of reach of children. O verdose warning : In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Ouick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	not notice any signs or symptoms.  Directions take only asd rected — see 0 verdose warning only use the dose cup provided donct exceed 4d oses per 24 hrs			
Directions         ■ take only asd irected - see Overdose warning           ■ only use the dose cup provided         ■ do not exceed 4d oses per 24 hrs           adults & children 12 yrs         30 mLevery 6 hrs           children 4to under 12 yrs         aska doctor	adults & children 12 yrs & over 30 mL every 4 hrs children 6 bunder 12 yrs 15 mL every 4 hrs children 4 bunder 6 yrs ask adoctor children under 4 yrs do not use			
children under 4 yrs do not use <b>◀ Other information ■ each 30 mL contains:</b> sodium 39 mg ■ storeat 20-25 °C (68-77 °F)	Other information         each 15 mL contains: sod ium 7 mg         storeat 20-25 °C (68-77 °F)			

: 13305 SE CH

### EQUATE NITETIME DAYTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information							
Product Type	e	HUMAN OTC DRUG	Item Code (Source)		NDC:49035-733		
Packaging							
# Item C	ode	Package Description	n	Marketing Start Date	Marketing End Date		
1 NDC:49035-	733-02 1 in	1 CARTON; Type 0: Not a Combina	ation Product 08/15/2013				
Quantity of Parts							
Part # Package Quantity Total Product Qu					antity		
Part 1 1BOT	ГLE		355 mL				
Part 2 1BOT	ΓLE		355 mL				
Part 1 of	2						

## EQUATE NITETIME

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

#### **Product Information Route of Administration** ORAL **Active Ingredient/Active Moiety Basis of Strength** Strength **Ingredient Name** 650 mg ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN in 30 mL DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) **DEXTROMETHORPHAN** 30 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) HYDROBROMIDE in 30 mL DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE -12.5 mg DOXYLAMINE SUCCINATE UNII:95QB77JKPL) 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** 08/02/2011 OTC monograph final part341

#### Part 2 of 2

1 41 ( 2 01	-						
EQUATE	DAY T	IME C	OLD AND FLU MULTI S	SYM	IPTOM RELIE	EF	
acetaminoph	en, dextror	nethorpha	n hbr, phenylephrine hcl solution				
Product Inf	ormation						
Route of Adm	inistration	ORAL					
Active Ingr	edient/Ac						
		Ingre	edient Name		Basis of Stre	ngth	Strength
ACETAMINOP	HEN (UNII: 3	362O9ITL91	D) (ACETAMINOPHEN - UNII:362O9ITL9	D)	ACETAMINOPHEN		325 mg in 15 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9KYH)DEXTROMETHORPHAN(DEXTROMETHORPHAN - UNII:7355X3ROTS)HYDROBROMIDE						IAN	10 mg in 15 mL
	PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -       PHENYLEPHRINE         JUNII: 1WS297W6 MV)       HYDRO CHLO RIDE					5 mg in 15 mL	
Inactive Ing	radiants						
macuve mg	reulents		Ingredient Name			St	rength
BUTYLATED	IVDRO XVA	NISOLE (U	NII: REK4960K2U)			51	rengen
EDETATE DISC							
FD&C YELLO							
GLYCERIN (UI	NII: PDC6A3	C0OX)					
SO DIUM PHO	SPHATE, MO	ONOBASIC	(UNII: 3980JIH2SW)				
POLYETHYLE	NE GLYCO	L (UNII: 3W	'JQ0SDW1A)				
PROPYLENE C	GLYCOL (U	NII: 6 DC 9 Q	167V3)				
WATER (UNII:	059QF0KO0	)R)					
SACCHARIN S	<b>O DIUM</b> (UN	II: SB8ZUX	40 TY)				
SUCROSE (UN							
XANTHAN GU	•	,					
MENTHOL (UN	NII: L7T10EIF	23A)					
Product Ch	aracteris	tics					
Color ORANGE (clear)		Score					
Shape				Size			
		MENTHOL	(with fruit)	Imprint Code			
Contains							
Packaging							
# Item Code		Pac	kage Description	Mar	keting Start Date	Marketing	g End Date
1	1 in 1 CAR						

1 35	5 mL in 1 BOTTLE; Type	0: Not a Combination Product				
Marketing Information						
Marketing Categ	ory Application Nu	umber or Monograph Citati	on Marketing Start Dat	e Marketing End Date		
OTC monograph fin	al part341		06/08/2006			
Marketing Information						
Marketing Categ	ory Application Nu	umber or Monograph Citati	on Marketing Start Dat	e Marketing End Date		
OTC monograph fin	al part341		08/15/2013			

Labeler - Wal-Mart Stores Inc (051957769)

Revised: 12/2018

Wal-Mart Stores Inc