TUSSIN DM MAX DAYTIME NIGHTTIME- dextromethorphan hbr, doxylamine succinate, guaifeses in CVS Pharmacy

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.

CVS Pharmacy, Inc. Tussin DM Drug Facts

Active ingredients (in each 20 mL) - NIGHTTIME

Dextromethorphan HBr, USP 30 mg Doxylamine succinate, USP 12.5 mg

Purposes

Cough suppressant Antihistamine

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- controls the impulse to cough to help you sleep

Warnings

Do Not Use

- to make a child sleepy
- 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

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

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- do not use more than directed
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign 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).

Directions

- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- do not take more than 4 doses in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	20 mL every 6 hours
children under 12 years	do not use

Other information

- each 20 mL contains: sodium 11 mg
- store at 20-25°C (68-77°F)

Inactive Ingredients

anhydrous citric acid, benzoic acid, benzyl alcohol, carboxymethylcellulose sodium, FD&C blue #1, FD&C red #40, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-800-719-9260

Active ingredients (in each 20 mL) - DAYTIME

Dextromethorphan HBr, USP 20 mg

Guaifenesin, USP 400 mg

Purposes

Cough suppressant Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings

Do not use

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

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if

cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign 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).

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- this adult product is not intended for use in children under 12 years of age

age dose	
----------	--

adults and children 12 years and over	20 mL every 4 hours
children under 12 years	do not use

Other information

- each 20 mL contains: sodium 13 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive Ingredients

acetic acid, anhydrous citric acid, carboxymethylcellulose sodium, FD&C blue no. 1, FD&C red no. 40, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

DAY & NIGHT COMBO PACK

Compare to the active ingredients in Robitussin® Maximum Strength Cough + Chest Congestion DM

MAXIMUM STRENGTH

MAXIMUM STRENGTH FOR MUCUS RELIEF

Non-Drowsy

See New Dosing

 $Tuss in\, DM$

DEXTROMETHORPHAN HBr

Cough suppressant

GUAIFENESIN

Expectorant

Adult Cough & Chest Congestion

Relieves:

Cough

Chest congestion

Mucus

Alcohol free

Raspberry & Menthol Flavor

For Ages 12 & Over

Dosage cup provided

Actual Bottle Size on Side Panel

Compare to the active ingredients in Robitussin® Maximum Strength Nighttime Cough DM

MAXIMUM STRENGTH

Nighttime See New Dosing Tussin DM DEXTROMETHORPHAN HBr Cough suppressant DOXYLAMINE SUCCINATE Antihistamine Adult Cough & Antihistamine Relieves: Cough Itchy throat Runny nose Alcohol free Raspberry, Blackberry & Menthol Flavor For Ages 12 & Over Dosage cup provided Actual Bottle Size on Side Panel 4 FL OZ (118 mL) + 4 FL OZ (118 mL) TOTAL 8 FL OZ (236 mL)



-

BAND IS BROKEN OR MISSING				
MAXIMU M STRENGTH Nighttime MG nissenine Adult Cough & Antihistamine	MAXIMUM STRENGTH FOR MUCUS RELIEF Non-Drowsy Manit Cough & Chest Congestion Adult Cough & Chest Congestion			
laximum Strength Tussin DM Adult Cough : Chest Congestion	Maximum Strength Nighttime Tussin DM Adult Cough & Antihistamine	Prove Freety (and Second		
	within 6 hours of each other.	Drug Facts (continued) Stop use and ask a doctor if cough lasts for more		
Drug Facts Active ingredients Purposes	Drug Facts Active ingredients Purposes	than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.		
<i>(in each 20 mL)</i> Dextromethorphan HBr, USP 20 mgCough suppressant Guaifenesin, USP 400 mgExpectorant	(<i>in each 20 mL</i>) Dextromethorphan HBr, USP 30 mgCough suppressant Doxylamine succinate, USP 12.5 mgAntihistamine	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		
Uses temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes	Uses temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:	right away (1-800-222-1222). Directions ■ measure only with dosing cup provided ■ keep dosing cup with product		
Warnings Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or	■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat ■ controls the impulse to cough to help you sleep	 mL = milliliter do not take more than 4 doses in any 24-hour period this adult product is not intended for use in children under 12 years of age 		
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	<i>Warnings</i> Do not use ■ to make a child sleepy	age dose adults and children 20 mL 12 years and over every 6 hours		
taking this product.	If you are now taking a prescription monoamine syldene inhibitor (MAQI) (sectors drugs for depression)	children under 12 years do not use		
Ask a doctor before use if you have cough that occurs with too much phlegm (mucus) cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema	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	Other information each 20 mL contains: sodium 11 mg store at 20-25°C (68-77°F)		
Stop use and ask a doctor if cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign 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	an MAOI, ask a doctor or pharmacist before taking this product. Ask a doctor before use if you have trouble urinating due to an enlarged prostate gland glaucoma cough that occurs with too much phlegm (mucus) a breathing problem such as emphysema or chronic	Inactive ingredients anhydrous citric acid, benzoic acid, benzyl alcohol, carboxymethylcellulose sodium, FD&C blue #1, FD&C red #40, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum		
medical help or contact a Poison Control Center right	bronchitis	Questions or comments? 1-800-719-9260		
away (1-800-222-1222). Directions do not take more than 6 doses in any 24-hour period measure only with dosing cup provided keep dosing cup with product mL = milliliter this adult product is not intended for use in children under 12 years of age	 persistent or chronic cough such as occurs with smoking, asthma, or emphysema Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers When using this product do not use more than directed marked drowsiness may occur avoid alcoholic drinks 	*These products are not manufactured or distributed by Pfizer, distributor of Robitussin [®] Maximum Strength Cough + Chest Congestion DM and Robitussin [®] Maximum Strength Nighttime Cough DM. Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 © 2018 CVS/pharmacy		
age dose adults and children 20 mL 12 years and over every 4 hours children under 12 years do not use	 alcohol, sedatives, and tranquilizers may increase drowsiness be careful when driving a motor vehicle or operating machinery excitability may occur, especially in children 	CVS.com 1-800-SHÓP CVS V-16430 CVS Quality Money Back Guarantee		



9Z212 17 C2

- ----

-

TUSSIN DM MAX DAYTIME NIGHTTIME dextromethorphan hbr, doxylamine succinate, guaifesesin kit								
devicement of phan not, doxyamme succinate, guaneses in Ka								
Product Informati	ion							
	HUMAN O		Itom Code (6	Source)	NI	DC:69842-92	20	
Product Type	HUMAN U	IC DRUG	Item Code (S	source)	INL	JC:09842-92	19	
Packaging								
# Item Code]	Package Descriptio	n	Marketi	ng Start Date	Marketin	g End Date	
1 NDC:69842-929-12		; Type 0: Not a Combin		07/20/201	0		0	
Quantity of Parts								
	Package Qua	ntity		Tota	l Product Qua	ntity		
Part 1 1BOTTLE			118 mL					
Part 2 1 BOTTLE			118 mL					
Part 1 of 2								
TUSSIN DM								
dextromethorphan h	br, doxylamin	e succinate solution	l					
							_	
Product Informati	ion							
Item Code (Source)		NDC:69842-699						
Route of Administrat	dministration ORAL							
Active Ingredient/Active Moiety								
Ingredient Name			71775	DI	Basis of Stre	-	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 H (DEXTROMETHORPHAN - UNII:7355X3ROTS)			(YH)		CXTROMETHORPI DROBROMIDE	HAN	30 mg in 20 mL	
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAM UNII:95QB77JKPL)		INE -	DC	OXYLAMINE SUC	CINATE	12.5 mg in 20 mL		
Inactive Ingredie	nts							
		Ingredient Na	ame			S	strength	
ANHYDRO US CITRIC	ACID (UNII: XF4	417D3PSL)						

Active Ing	gredient/	Active Moi	ety			
Toute of At	. ministi at	1011				
Route of Ad		ion	ORAL			
Item Code			NDC:69842-819			
Product I	nformati	on				
dextrometh	norphan hl	br, guaifenes	in solution			
TUSSIN		- 6				
Part 2 o	f 2					
OTC monogr		part341			06/25/2018	
Marketing	-		on Number or Monog	graph Citation	Marketing Start Date	Marketing End Dat
Marketi	ing Info	rmation				
1		118 mL in 1 BO	TTLE; Type 0: Not a C	ombination Product		
		1 in 1 CARTON				
# Item			Package Descripti	on	Marketing Start Date	Marketing End Da
Packagin	-					
Contains						
Flavor			FRUII	Imprint Code		
Shape			FRUIT	Size		
			κed			
Color	murucie	10 1105	RED	Score		
Product C	haracter	ristics				
		TTV12P4NEE)				
SUCRALOS						
SORBITOL			•			
		UNII: OJ245FE5	EU)			
WATER (UN						
		(UNII: 6DC9Q)				
		COL (UNII: 3W	JO0SDW1A)			
GLYCERIN (MENTHOL (
		III: WZB9127XC	A)			
		III: H3R47K3TB				
			DIUM (UNII: K679OBS	5311)		
		JNII: LKG8494				

# Item Cod	e	Package Desc	ription	Marketing Start Date	Marketing End Da
Packaging					
Contains					
Flavor		FRUIT	Imprint Code		
Shape			Size		
Color		RED	Score		
Product Chai	acteristics				
XANTHAN GUM	(UNII: 1 1 V 12P4N)	cc)			
SUCRALOSE (U)					
SORBITOL (UN		4)			
SODIUM CITRA		JULR)			
SODIUM BENZO					
WATER (UNII: 05					
PROPYLENE GL		C9Q167V3)			
		I: 3WJQ0SDW1A)			
MENTHOL (UNII					
GLYCERIN (UNI					
FD&C RED NO.	10 (UNII: WZB912	27XOA)			
FD&C BLUE NO					
		E SODIUM (UNII: K679	90BS311)		
ANHYDROUS CI					
0		Ingredie	nt Name		Strength
Inactive Ingr	edients				
GUAIFENESIN (C	лип. 435 W/ 451 V	(GOAIFENESIN - OI	(II.455)((7451)(Q)	GUAIFENESIN	in 20 mL
•	ESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII: 495W7451VQ)			GUAIFENESIN	400 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)			DEXTROMETHORPHA HYDROBROMIDE	AN 20 mg in 20 mL	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	0 5/0 4/20 18	

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph finalpar34107/20/201807/20/2018

Revised: 10/2018

CVS Pharmacy