COUGH DM- dextromethorphan polistirex suspension, extended release Praxis, LLC

Walgreen Co. Cough DM Drug Facts

Active ingredient (in each 5 mL)

Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide

Purpose

Cough suppressant

Uses

temporarily relieves

- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the impulse to cough to help you get to sleep

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.

Allergy Alert:Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

Ask a doctor before use if you have

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

Stop use and ask a doctor if

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- cough lasts more than 7 days, cough comes back, or occurs with fever, 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-

Directions

- shake bottle well before use
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor

adults and children 12	10 mL every 12 hours,
years of age	not to exceed 20 mL in 24
and over	hours
children 6 to under 12	5 mL every 12 hours,
years of age	not to exceed 10 mL in 24
	hours
children 4 to under 6 years	2.5 mL every 12 hours,
of age	not to exceed 5 mL in 24 hours
children under 4 years of	do not use
age	

Other information

- each 5 mL contains: sodium 5 mg
- store at 20° to 25°C (68° to 77°F)
- dosing cup provided

Inactive ingredients

artificial grape flavor, D&C Red #30 aluminum lake, FD&C Blue #1 aluminum lake, glycerin, high fructose corn syrup, methylparaben, polysorbate 80, polyvinyl acetate, povidone, propylparaben, purified water, sodium metabisulfite, sodium polystyrene sulfonate, sucrose, tartaric acid, tragacanth gum, triacetin, xanthan gum

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

VALUE SIZE

Walgreens

WALGREENS PHARMACIST RECOMMENDED

Compare to the active ingredient in Delsym ®

12-HOUR COUGH RELIEF

Cough DM

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION / COUGH SUPPRESSANT

12 Hour

Day or Night

- Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions
- Alcohol free

Dosing cup included

- 5 FL OZ (148 mL)
- Grape flavored liquid



Produ Route Route Activ DEXTR DEXTR Inact FD&C GLYCE HIGH I METHY POLYS POLYS POLYS POLYS POLYS POLYS POLYS SODIU SODIU SUCRO	ROMETHORPH ROMETHORPH ELUE NO. 1 ERIN (UNII: PE FRUCTOSE C YLPARABEN SORBATE 80	stration ent/Active I Ingrec HAN HYDROBE AN - UNII:7355X3 dients (UNII: H3R47K3	dient Name ROMIDE (UNII: 9D2RTI9 BROTS) Ingredient Nam TBD)	(үн)			S68-260 Strength 30 mg in 5 mL trength
Produ Route Activ DEXTR (DEXTR Inact Inact GLYCE HIGH I METH POLYS POLYS POLYS POLYS POLYS POLYS POLYS SODIU SODIU SUCRO	uct Type e of Admini /e Ingredi ROMETHORPH COMETHORPH tive Ingre BLUE NO. 1 ERIN (UNII: PE FRUCTOSE C YLPARABEN SORBATE 80	stration ent/Active I Ingred HAN HYDROBE AN - UNII:7355X dients (UNII: H3R47K3 006A3C00X) CORN SYRUP (L	ORAL Moiety dient Name ROMIDE (UNII: 9D2RT19) 3ROTS) Ingredient Nam TBD)	(үн)	Basis	of Strength ETHORPHAN OMIDE	Strength 30 mg in 5 mL
Route Activ DEXTR (DEXTR Inact FD&C GLYCE HIGH I METHY POLYS POLYS POLYS POLYS POLYS POLYS POLYS SODIU SODIU SODIU	e of Admini /e Ingredi ROMETHORPH COMETHORPH tive Ingre BLUE NO. 1 ERIN (UNII: PE FRUCTOSE C YLPARABEN SORBATE 80	ent/Active Ingrec HAN HYDROBE AN - UNII:7355X: dients (UNII: H3R47K3 DC6A3C0OX) CORN SYRUP (L	ORAL Moiety dient Name ROMIDE (UNII: 9D2RT19) 3ROTS) Ingredient Nam TBD)	(үн)	Basis	of Strength ETHORPHAN OMIDE	Strengtl 30 mg in 5 mL
Activ DEXTR (DEXTR Inact FD&C GLYCE HIGH I METHY POLYS POLYS POLYS POLYS POLYS POLYS POLYS SODIU SODIU SODIU	Ve Ingredi ROMETHORPH ROMETHORPH tive Ingre BLUE NO. 1 ERIN (UNII: PE FRUCTOSE C YLPARABEN SORBATE 80	ent/Active Ingrec HAN HYDROBE AN - UNII:7355X: dients (UNII: H3R47K3 DC6A3C0OX) CORN SYRUP (L	Moiety dient Name ROMIDE (UNII: 9D2RTI9 BROTS) Ingredient Nam TBD)		DEXTROM	ETHORPHAN OMIDE	30 mg in 5 mL
DEXTR (DEXTR (DEXTR Inact FD&C GLYCE HIGH I METH' POLYS POLYS POLYS POLYS POLYS POLYS POLYS POLYS SODIU SODIU SODIU SUCRO	ROMETHORPH ROMETHORPH ELUE NO. 1 ERIN (UNII: PE FRUCTOSE C YLPARABEN SORBATE 80	Ingred HAN HYDROBR AN - UNII:7355X dients (UNII: H3R47K3 DC6A3C0OX) CORN SYRUP (L	dient Name ROMIDE (UNII: 9D2RTI9 BROTS) Ingredient Nam TBD)		DEXTROM	ETHORPHAN OMIDE	30 mg in 5 mL
DEXTR (DEXTR (DEXTR Inact FD&C GLYCE HIGH I METH' POLYS POLYS POLYS POLYS POLYS POLYS POLYS POLYS SODIU SODIU SODIU SUCRO	ROMETHORPH ROMETHORPH ELUE NO. 1 ERIN (UNII: PE FRUCTOSE C YLPARABEN SORBATE 80	Ingred HAN HYDROBR AN - UNII:7355X dients (UNII: H3R47K3 DC6A3C0OX) CORN SYRUP (L	dient Name ROMIDE (UNII: 9D2RTI9 BROTS) Ingredient Nam TBD)		DEXTROM	ETHORPHAN OMIDE	30 mg in 5 mL
(DEXTR Inact FD&C GLYCE HIGH I METHY POLYS POLYS POLYS POVID PROPY WATE SODIU SODIU SODIU	tive Ingre BLUE NO. 1 ERIN (UNII: PE FRUCTOSE C YLPARABEN SORBATE 80	HAN HYDROBR AN - UNII:7355X dients (UNII: H3R47K3 DC6A3C0OX) CORN SYRUP (L	ROMIDE (UNII: 9D2RTI9 BROTS) Ingredient Nam TBD)		DEXTROM	ETHORPHAN OMIDE	30 mg in 5 mL
FD&C GLYCE HIGH I METH' POLYS POLYS POVID PROPY WATE SODIU SODIU SUCRO	BLUE NO. 1 ERIN (UNII: PE FRUCTOSE C YLPARABEN SORBATE 80	(UNII: H3R47K3 DC6A3C0OX) CORN SYRUP (L	TBD)	e		S	trength
GLYCE HIGH I METHY POLYS POVID POVID PROPY WATE SODIU SODIU SUCRO	ERIN (UNII: PE Fructose (Ylparaben Sorbate 80	OC6A3C0OX) C ORN SYRUP (L	TBD)	e		S	trength
GLYCE HIGH I METHY POLYS POVID POVID PROPY WATE SODIU SODIU SUCRO	ERIN (UNII: PE Fructose (Ylparaben Sorbate 80	OC6A3C0OX) C ORN SYRUP (L					
HIGH I METHY POLYS POLYS POVID PROPY WATE SODIU SODIU SUCRO	FRUCTOSE (YLPARABEN SORBATE 80	CORN SYRUP (L					
METHY POLYS POLYV POVID PROPY WATE SODIU SODIU SUCRO	YLPARABEN Sorbate 80						
POLYS POLYV POVID PROPY WATE SODIU SODIU SUCRO	SORBATE 80	(UNII: A2I8C7HI9	JNII: XY6UN3QB6S)				
POLYV POVID PROPY WATE SODIU SODIU SUCRO			ЭТ)				
POVID PROPY WATE SODIU SODIU SUCRO	VINYI ACETA	(UNII: 60ZP39Z	ZG8H)				
PROPY WATE SODIU SODIU SUCRO		TE (UNII: 32K49	97ZK2U)				
WATE SODIU SODIU SUCRO	ONE, UNSPE	CIFIED (UNII: F	Z989GH94E)				
SODIU SODIU SUCRO	YLPARABEN	(UNII: Z8IX2SC1	OH)				
SODIU SUCRO	R (UNII: 059Q	F0KO0R)					
SUCRO	JM METABIS	ULFITE (UNII: 4)	VON5FNS3C)				
	JM POLYSTY	RENE SULFON	ATE (UNII: 1699G8679Z)			
тлртл	OSE (UNII: C1	51H8M554)					
IANIA	ARIC ACID (U	NII: W4888I119H	1)				
TRAGA	ACANTH (UNI	l: 2944357020)					
TRIACETIN (UNII: XHX3C3X673)							
XANTHAN GUM (UNII: TTV12P4NEE)							
D&C R	RED NO. 30 (UNII: 2S42T2808	8B)				
Prod	luct Chara	acteristics					
Color			purple	Score			
Shape				Size			
Flavo							
Conta				Imprint Code			
Conta	21115						
Pack	aging						
# Ite	_	Pac	ckage Description		Marketing S Date		eting End Date
1 NDC	em Code				07/01/2015	08/01/202	22

AN	IDA	ANDA091135	07/01/2015		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Marketing Information					
2		148 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:59368-260- 01	1 in 1 CARTON	05/20/2017		
1		89 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Labeler - Praxis, LLC (016329513)

Establishment			
Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	label(59368-260), pack(59368-260), manufacture(59368-260)

Revised: 1/2023

Praxis, LLC