

## **DG HEALTH TUSSIN- dextromethorphan hbr, doxylamine succinate solution Dolgenercorp, LLC**

*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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### **Dolgenercorp, LLC Tussin Drug Facts**

#### **Active ingredients (in each 20 mL)**

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?**

**1-888-309-9030**

## **Package/Label Principal Display Panel**

DG™ |health

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

For Ages 12 & Over

Adult

Maximum Strength

Tussin

Cough Suppressant (Dextromethorphan HBr)

Antihistamine (Doxylamine Succinate)

Max Strength Night Time Cough Control

Relieves:

- Cough
- Itchy Throat
- Runny Nose

Night Time Cough DM

Same Effective Nighttime Relief\*\*

4 FL OZ (118 mL)

\*\*Compared to our previous (10 mL) formula



## DG HEALTH TUSSIN

dextromethorphan hbr, doxylamine succinate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-709
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 20 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 20 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**Product Characteristics**

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-709-26	1 in 1 CARTON	09/10/2018	
1		118 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	09/10/2018	

