

**ROBITUSSIN 12 HOUR COUGH RELIEF- dextromethorphan polistirex suspension, extended release**

**GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

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***Drug Facts***

***Active ingredient (in each 5 mL)***

Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide, USP

***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 1-800-222-1222.

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

### ***Other information***

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

### ***Inactive ingredients*** (Grape flavor)

D&C red no. 30, FD&C blue no. 1, flavor, 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

### ***Inactive ingredients*** (Orange flavor)

D&C red no. 30, D&C yellow no. 10, flavor, 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?***

call weekdays from 9 AM to 5 PM EST at **1-800-762-4675**.  
You may also report side effects to this number.

For most recent product information, **visit [www.robitussin.com](http://www.robitussin.com)**

Distributed by: Pfizer, Madison, NJ 07940 USA

## **PRINCIPAL DISPLAY PANEL**

**Robitussin®**

**EXTENDED-RELEASE**

**12 Hour**

**Cough Relief**

**DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION (Cough Suppressant)**

**12 Hour**

**Cough Relief**

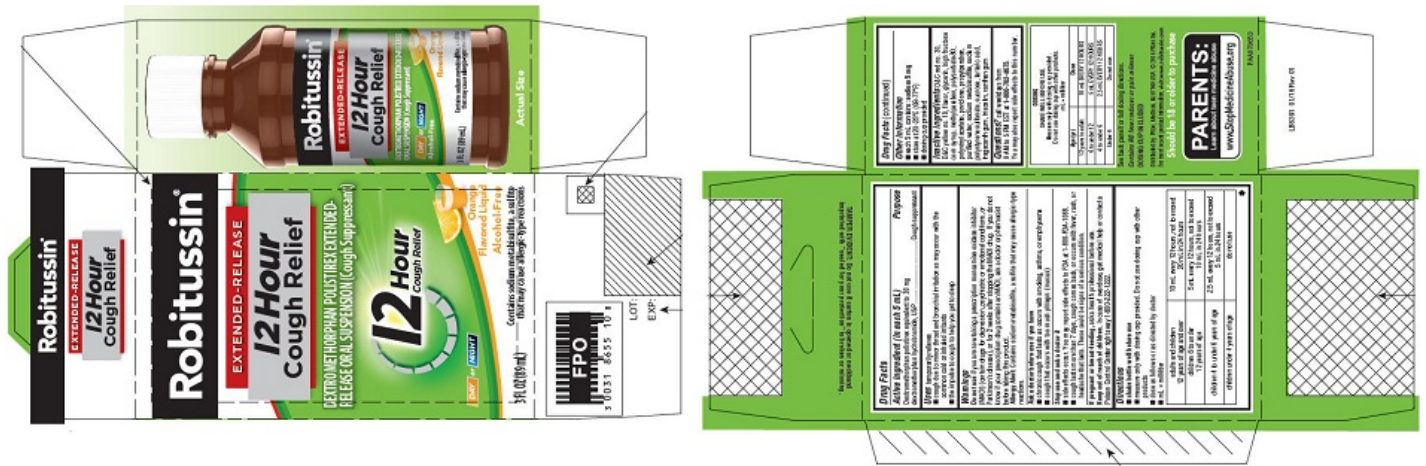
**DAY or NIGHT**

**Orange  
Flavored Liquid**

**Alcohol-Free**

3 FL OZ (89 mL)

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



**PRINCIPAL DISPLAY PANEL**

**NEW SIZE!**

**Robitussin®**

**EXTENDED-RELEASE**

**12 Hour  
Cough Relief**

**DEXTROMETHORPHAN POLISTIREX EXTENDED-  
RELEASE ORAL SUSPENSION (Cough Suppressant)**

**12 Hour  
Cough Relief**

**DAY or NIGHT**

**Orange  
Flavored Liquid**

**Alcohol-Free**

**5 FL OZ  
(148 mL)**

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



**12 Hour  
Cough Relief**

**DEXTROMETHORPHAN POLISTIREX EXTENDED-  
RELEASE ORAL SUSPENSION (Cough Suppressant)**

**12 Hour  
Cough Relief**

**DAY or NIGHT**

**Grape  
Flavored Liquid**

**Alcohol-Free**

**5 FL OZ  
(148 mL)**

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



<b>ROBITUSSIN 12 HOUR COUGH RELIEF</b>			
dextromethorphan polistirex suspension, extended release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0031-8655
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	POLISTIREX (UNII: 5H9W9GTW27)		
	D&C RED NO. 30 (UNII: 2S42T2808B)		
	D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		

GLYCERIN (UNII: PDC6A3C00X)
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)
METHYLPARABEN (UNII: A2I8C7H9T)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
POLYVINYL ACETATE (UNII: 32K497ZK2U)
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)
SUCROSE (UNII: C151H8M554)
TARTARIC ACID (UNII: W4888I119H)
TRAGACANTH (UNII: 2944357O2O)
TRIACETIN (UNII: XHX3C3X673)
WATER (UNII: 059QF0K00R)
XANTHAN GUM (UNII: TTV12P4NEE)

### Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8655-10	1 in 1 CARTON	07/01/2015	
1		89 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
ANDA	ANDA091135	07/01/2015	

## ROBITUSSIN 12 HOUR COUGH RELIEF

dextromethorphan polistirex suspension, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8754
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
POLISTIREX (UNII: 5H9W9GTW27)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ACETATE (UNII: 32K497ZK2U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
SUCROSE (UNII: C151H8M554)	
TARTARIC ACID (UNII: W4888I119H)	
TRAGACANTH (UNII: 2944357O2O)	
TRIACETIN (UNII: XHX3C3X673)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8754-15	1 in 1 CARTON	07/05/2016	
1		148 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
ANDA	ANDA091135	07/05/2016	

## ROBITUSSIN 12 HOUR COUGH RELIEF

dextromethorphan polistirex suspension, extended release

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8753
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Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
POLISTIREX (UNII: 5H9W9GTW27)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ACETATE (UNII: 32K497ZK2U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
SUCROSE (UNII: C151H8M554)	
TARTARIC ACID (UNII: W4888I119H)	
TRAGACANTH (UNII: 2944357O2O)	
TRIACETIN (UNII: XHX3C3X673)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8753-03	1 in 1 CARTON	07/01/2015	
1		89 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
ANDA	ANDA091135	07/01/2015	



# ROBITUSSIN 12 HOUR COUGH RELIEF

dextromethorphan polistirex suspension, extended release

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8755
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
POLISTIREX (UNII: 5H9W9GTW27)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
METHYLPARABEN (UNII: A2I8C7H9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ACETATE (UNII: 32K497ZK2U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
SUCROSE (UNII: C151H8M554)	
TARTARIC ACID (UNII: W4888I119H)	
TRAGACANTH (UNII: 2944357O2O)	
TRIACETIN (UNII: XHX3C3X673)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8755-15	1 in 1 CARTON	07/05/2016	
1		148 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
ANDA	ANDA091135	07/05/2016	

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 10/2020

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC