

**REXALL DAYTIME NIGHTTIME COLD FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl  
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 Daytime Nighttime Cold/Flu Drug Facts**

**Active ingredients (in each softgel) - Nighttime Cold & Flu**

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

**Active ingredients (in each softgel) - Daytime Cold & Flu**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Purpose - Nighttime Cold & Flu**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

**Purpose - Daytime Cold & Flu**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

**Uses - Nighttime Cold & Flu**

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- minor aches and pains
- sore throat
- headache
- runny nose and sneezing

- fever

## **Uses - Daytime Cold & Flu**

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- minor aches and pains
- sore throat
- headache
- nasal congestion
- fever

## **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, lasts 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 - Nighttime Cold & Flu**

- liver disease
- glaucoma

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

### **Ask a doctor before use if you have - Daytime Cold & Flu**

- liver disease
- diabetes
- heart disease
- high blood pressure
- thyroid disease
- 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 - Nighttime Cold & Flu**

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

### **Ask a doctor or pharmacist before use if you are - Daytime Cold & Flu**

taking the blood thinning drug warfarin

### **When using this product - Nighttime Cold & Flu**

- 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

### **When using the product - Daytime Cold & Flu**

**do not use more than directed**

### **Stop use and ask a doctor if - Nighttime Cold & Flu**

- 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.

### **Stop use and ask a doctor if - Daytime Cold & Flu**

- you get nervous, dizzy or sleepless
- pain, nasal congestion 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 - Nighttime Cold & Flu**

- take only as directed – see overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 softgels with water every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

**Directions - Daytime Cold & Flu**

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adults & children 12 yrs & over	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

**Other information**

- store at 20-25°C (68-77°F)

**Inactive ingredients - Nighttime Cold & Flu**

D&C yellow no. 10, edible ink\*, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingret

**Inactive ingredients - Daytime Cold & Flu**

edible ink\*, FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution \*may contain this

ingredient

## **Principal Display Panel**

Since 1903 Rexall®

NON-DROWSY

Daytime Cold/Flu

ALCOHOL-FREE & ANTIHISTAMINE-FREE

ACETAMINOPHEN.....Pain reliever/Fever reducer

DEXTROMETHORPHAN HBr...Cough suppressant

PHENYLEPHRINE HCl.....Nasal decongestant

For relief of

- aches, fever, cough
- nasal congestion

actual size

Nighttime

Cold/Flu

ACETAMINOPHEN.....Pain reliever/Fever reducer

DEXTROMETHORPHAN HBr...Cough suppressant

DOXYLAMINE SUCCINATE..... Antihistamine

For relief of

- aches, fever, cough
- sneezing, runny nose

actual size

20 DAYTIME SOFTGELS

COMBO PACK 40 TOTAL SOFTGELS

20 NIGHTTIME SOFTGELS

Since 1903  
**Rexall**

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**Daytime**

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**Nighttime**

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For relief of  
• aches, fever, cough  
• sneezing, runny nose



20 DAYTIME SOFTGELS **COMBO PACK** 40 TOTAL SOFTGELS 20 NIGHTTIME SOFTGELS

**Nighttime Cold & Flu**

**Drug Facts**

**Active ingredients (in each softgel)**  
Acetaminophen 325mg.....Pain reliever/fever reducer  
Dextromethorphan HBr 15 mg.....Cough suppressant  
Doxylamine succinate 6.25 mg.....Antihistamine

**Purpose**

**Uses:** temporarily relieves common cold/flu symptoms:  
• cough due to minor throat and bronchial irritation  
• minor aches and pains • sore throat • headache  
• runny nose and sneezing • fever

**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 drug containing acetaminophen  
• 3 or more alcohol 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.

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**Drug Facts (continued)**

**Sore throat warning:** If sore throat is severe, lasts 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 or pharmacist before use if you have** • fever/disease • dizziness • cough that occurs with too much phlegm (mucus) • a breathing problem such as emphysema, chronic bronchitis • persistent or chronic cough as occurs with smoking, asthma, or emphysema • trouble breathing due to an enlarged prostate gland

**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 cautious 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.

**Drug Facts (continued)**

**Sore throat warning:** If sore throat is severe, lasts for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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• if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor or pharmacist before use if you have** • fever/disease • diabetes • heart disease • high blood pressure • thyroid disease • trouble breathing due to an enlarged prostate gland • cough that occurs with too much phlegm (mucus) • persistent or chronic coughs 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 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.

**Drug Facts (continued)**

**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  
• do not exceed 4 doses per 24 hrs  
adults & children 12 yrs & over 2 softgels with water every 6 hrs  
children 4 to under 12 yrs ask a doctor  
children under 4 yrs do not use

**Other information**

• store at 20-25°C (68-77°F)  
**Inactive ingredients:** D&C yellow no. 10, d&B pink, FD&C blue no. 1, gelatin, glycerin polyethylene glycol paraffin, polyethylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingredient

**Drug Facts (continued)**

**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.**

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**Other information**

• store at 20-25°C (68-77°F)  
**Inactive ingredients:** d&B pink, FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin polyethylene glycol paraffin, polyethylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingredient

58005 CR 04

**CODE AREA**



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DO NOT USE IF PLASTER UNIT IS BROKEN OR TORN

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100 MISSION RIDGE  
GOODLETTSVILLE, TN 37072

Made in Canada  
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CONVENIENT RECYCLING TAB

# REXALL DAYTIME NIGHTTIME COLD FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-580
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-580-05	1 in 1 CARTON; Type 0: Not a Combination Product	05/25/2014	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	10 BLISTER PACK	20
Part 2	10 BLISTER PACK	20

## Part 1 of 2

### REXALL NIGHTTIME COLD FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

## Product Information

<b>Route of Administration</b>	ORAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	GREEN (clear)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	056
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 BLISTER PACK; 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	05/25/2014	

## Part 2 of 2

### REXALL DAYTIME COLD FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

### Product Information

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	



<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	L994
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 BLISTER PACK; 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	05/25/2014	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/25/2014	

**Labeler** - Dolgencorp, LLC (068331990)