

# **DG HEALTH TUSSIN- acetaminophen, diphenhydramine hcl, phenylephrine hcl solution**

**Dolgencorp, 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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## **Dolgencorp, LLC Tussin Drug Facts**

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

Acetaminophen, USP 650 mg

Diphenhydramine HCl, USP 25 mg

Phenylephrine HCl, USP 10 mg

### **Purposes**

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

### **Uses**

- temporarily relieves these symptoms occurring with a cold or flu, hay fever, or other respiratory allergies:
- cough due to minor throat and bronchial irritation
- nasal congestion
- headache
- minor aches and pains
- sore throat
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose and throat
- temporarily reduces 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, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

### **Do not use**

- to sedate a child or 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.
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- if you have ever had an allergic reaction to this product or any of its ingredients

### **Ask a doctor before use if you have**

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- glaucoma
- trouble urinating due to an enlarged prostate gland
- 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 the blood thinning drug warfarin
- 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**

- you get nervous, dizzy or sleepless
- pain, cough, or nasal congestion 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). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- do not take more than 5 doses in any 24-hour period
- do not exceed recommended dosage. Taking more than the recommended dose (overdose) may cause serious liver damage.
- 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 11 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C red #40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triacetin

## Questions or comments?

**1-888-309-9030**

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

Compare to the active ingredients of Robitussin<sup>®</sup> Severe Multi-Symptom Cough Cold + Flu Nighttime

For Ages 12 & Over

CF Night Time MAX

Adult

Max Strength

Tussin

Pain Reliever/Fever Reducer (Acetaminophen)

Antihistamine/Cough Suppressant (Diphenhydramine HCl)

Nasal Decongestant (Phenylephrine HCl)

Severe

Multi-Symptom Cough Cold + Flu

Night Time

Relieves:

- Cough
- Sore Throat
- Body Aches
- Fever
- Nasal Congestion
- Runny Nose

4 FL OZ (118 mL)



## DG HEALTH TUSSIN

acetaminophen, diphenhydramine hcl, phenylephrine hcl solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-284
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 20 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients	
Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

Product Characteristics			
<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-284-26	1 in 1 CARTON	08/01/2016	
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	08/01/2016	

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

