

**DOCTOR MANZANILLA COUGH SUPPRESSANT AND NASAL DECONGESTANT -
diphenhydramine hydrochloride, phenylephrine hydrochloride solution
Mid Valley Pharmaceuticals 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.

Doctor Manzanilla Cough Suppressant and Nasal Decongestant

Drug Facts

Active ingredients (in each 5mL)

Diphenhydramine Hydrochloride 12.5mg

Phenylephrine Hydrochloride 5mg

Purpose

Antihistamine/Cough Suppressant

Nasal Decongestant

Uses:

Temporarily relieves

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever or other upper respiratory
- cough associated with a cold
- the cough reflex that causes coughing
- nasal congestion
- Promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure.

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.
- With any other product containing diphenhydramine, even one used on skin.
- **Do not exceed recommended dosage.**
- If nervousness, dizziness, or sleeplessness occurs, discontinue use and consult a doctor.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due an enlarged prostate gland
- cough that occurs that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or if cough is accompanied by excessive phlegm (mucus).

Ask a doctor or pharmacist

before use if you are taking sedatives or tranquilizers

When using this product:

- **do not exceed recommended dosage**
- may cause excitability especially in children
- may cause "drowsiness"; alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages while taking this product
- use caution when driving a motor vehicle or operating machinery.

Stop use and ask a doctor if:

- you get nervous, dizzy, or sleeplessness occurs
- symptoms do not improve within 7 days, tend to recur, 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.

Directions:

Do not take more than 6 doses in 24 hours.

Adults and children 12 years of age and over	2 teaspoonfuls (10mL) every 4 hours
Children 6 to under 12 years of age	1 teaspoonfuls (5mL) every 4 hours
Children under 6 years of age	Consult a doctor

Other information:

Store at controlled room temperature 15° - 30°C (59°-86°F). **Each dose contains** 10 mg sodium.

Inactive ingredients:

Citric Acid, Trisodium Citrate, Glycerin, Propylene Glycol, Sorbitol, Sucralose, Propyl Gllate, Edetate Sodium, Sodium Benzoate, Chamomile Flavor, Oregano Extract, Yellow No. 5

To report serious side effects associated with the use of this product call the Poison Control Center.

Package Label

Doctor Manzanilla

COUGH SUPPRESSANT & NASAL DECONGESTANT

I RECCOMEND IT

LAURA FLORES
4 FL OZ. (118 ml)

100%
Manzanilla Natural

Relieves!

Cough

Nasal

Decongestant

Throat

Irritation

Sneeze

Bronchial Irritation

Itching watery eyes

Distributed by: Midvalley Pharmaceuticals
Raymondville, TX 78580

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Drug Facts

Active Ingredients (in each 5mL)
Diphenhydramine Hydrochloride 12.5mg.....Antihistamine/Cough Suppressant
Phenylephrine Hydrochloride 5mg.....Nasal Decongestant

Purpose
Temporarily relieves:
runny nose ■ sneezing ■ itching of the nose or throat ■ itchy, watery eyes due to hay fever or other upper respiratory ■ cough associated with a cold ■ the cough reflex that causes coughing ■ nasal congestion ■ Promotes nasal and/or sinus drainage ■ temporarily relieves sinus congestion and pressure.

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. ■ With any other product containing diphenhydramine, even one used on skin. ■ **Do not exceed recommended dosage.** ■ nervousness, dizziness, or sleepiness occurs, discontinue use and consult a doctor.

Ask a doctor before use if you have: ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or if cough is accompanied by excessive phlegm (mucus).

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

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100% Manzanilla Natural Alivia!

Tos
Congestion Nasal
Irritacion de Garganta
Estornudo
Irritacion Bronquial
Ojos llorozos por fiebre de heno

Doctor Manzanilla

COUGH SUPPRESSANT & NASAL DECONGESTANT

JARABE PARA LA TOS Y CONGESTION SYRUP FOR COUGH AND CONGESTION

YO LO RECOMIENDO IT

LAURA FLORES
4 FL OZ. (118 ml)

100% Manzanilla Natural Relieves!

Cough
Nasal Decongestant
Throat Irritation
Sneeze
Bronchial Irritation
Itching watery eyes

Doctor Manzanilla

Distributed by: Midvalley Pharmaceuticals
Raymondville, TX 78580

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DOCTOR MANZANILLA COUGH SUPPRESSANT AND NASAL DECONGESTANT

diphenhydramine hydrochloride, phenylephrine hydrochloride solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:62558-001

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62558-001-18	1 in 1 CARTON		
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	03/04/2014	

Labeler - Mid Valley Pharmaceuticals LLC (079227119)

Revised: 6/2015

Mid Valley Pharmaceuticals LLC