

**DOCTOR MANZANILLA ALLERGY AND DECONGESTANT RELIEF- doctor manzanilla
allergy and decongestant relief syrup
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.

DRUG LABEL

DRUG FACTS:

ACTIVE INGREDIENTS (IN EACH 5ML)

Diphenhydramine Hydrochloride 12.5mg

Phenylephrine Hydrochloride 5mL

PURPOSE:

Antihistamine

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 allergies or allergic rhinitis
- 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:

Warnings:

Do not use - Do not exceed recommended dosage.

- If nervousness, dizziness, or sleeplessness occurs, discontinue use and consult a doctor.
- 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. If symptoms do not improve within seven days or are accompanied by fever, 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 marked 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 less than 5 mg sodium.

INACTIVE INGREDIENTS:

Caramel Color, Citric Acid, Glycerin, Natural Chamomile, Natural Cherry Flavor, Propylene Glycol, Purified Water, Sorbitol, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, Stevia, Sucralose.

ADVERSE REACTIONS:

In case of overdose, get medical help or contact a Poison Control Center right away.

Doctor Manzanilla Allergy Carton Label

24 / mm

100% Manzanilla Natural / Natural Chamomile
Para el Gusto de / For a Great Soothing Taste
Alivio / Relief!
Alergias / Allergy

Congestión Nasal / Nasal Decongestant

Irritación de Garganta / Itchy Throat

Estornudo / Sneezing

Ojos llorosos por fiebre / watery eyes

Antihistamínico / Antihistamine

100% Natural Chamomile

Doctor Manzanilla

ALLERGY & DECONGESTANT RELIEF

ALIVIO DE ALERGIAS & DESCONGESTIONANTE

4 FL OZ. (118 mL)
Diphenhydramine HCl (Antihistamine)
Phenylephrine HCl (Nasal Decongestant)

Drug Facts

Active ingredients (in each 5mL) Purpose
Diphenhydramine Hydrochloride 12.8 mg Antihistamine
Phenylephrine Hydrochloride 5 mg Nasal Decongestant

Uses: Temporarily relieves ■ running nose ■ sneezing ■ itching of the nose or throat ■ itchy, watery eyes due to hay fever or other upper respiratory allergies or allergic rhinitis ■ 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: ■ Do not exceed recommended dosage. If nervousness, dizziness, or sleeplessness occurs, discontinue use and consult a doctor. ■ 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 as a laxative. ■ If symptoms do not improve within seven days or are accompanied by fever, 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 feels such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or if cough is accompanied by excessive phlegm (mucus)

Drug Facts (continued)

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 marked "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.
For dosing use the enclosed dosage cup.

Adults and children 12 years of age and over	2 teaspoonfuls (10 mL) every 4 hours
Children 6 to under 12 years of age	1 teaspoonful (5 mL) 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).
Tamper Evident by full seal under cap. Do not use if seal is broken or missing.

Inactive ingredients:
Caramel Color, Citric Acid, Glycerin, Natural Chamomile Flavor, Natural Cherry Flavor, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, Sorbitol Solution, Stevia, Sucralose.

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

Distributed by: Midvalley Pharmaceuticals
Raymondville, TX 75858
Rev. 01/18

Lot: _____ Exp: _____

Distributed by: Midvalley Pharmaceuticals
Raymondville, TX 75858

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Doctor Manzanilla Allergy and Decongestant Carton

Doctor Manzanilla

ALLERGY

100% Natural Chamomile

Doctor Manzanilla

ALLERGY &

DECONGESTANT RELIEF

4 FL OZ. (118 ml)

Diphenhydramine HCl

(Antihistamine)

Phenylephrine HCl

(Nasal Decongestant)

100% Manzanilla Natural

Congestion Nasal

Doctor Manzanilla

100% Natural Chamomile

FOR A GREAT SOOTHING TASTE

Relieves!

Allergy

Nasal Decongestant

Itchy Throat

Sneezing

Itching watery eyes

Antihistamine

Doctor Manzanilla

Distributed by: Midvalley Pharmaceuticals
Raymondville, TX 78580

DOCTOR MANZANILLA ALLERGY AND DECONGESTANT RELIEF

doctor manzanilla allergy and decongestant relief syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62558-002
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	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CHAMOMILE (UNII: FGL3685T2X)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
STEVIA LEAF (UNII: 6TC6NN0876)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	brown (Caramel Color)	Score	
Shape		Size	
Flavor	CHERRY (Natural)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62558-002-04	1 in 1 CARTON	01/12/2017	
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	01/12/2017	

Labeler - Mid Valley Pharmaceuticals LLC (079227119)**Registrant** - Mid Valley Pharmaceuticals LLC (079227119)

Revised: 4/2020

Mid Valley Pharmaceuticals LLC