

M-DRYL- diphenhydramine hydrochloride liquid
Method 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.

M-Dryl

M-Dryl

Diphenhydramine Hydrochloride Oral Solution

Antihistamine

Cherry Flavor

RELIEVES

- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Throat due to Allergies

DO NOT USE IF TAMPER EVIDENT SEAL

UNDER CAP IS BROKEN OR MISSING

Alcohol Free

Each 5 mL (1 teaspoonful) contains:

Diphenhydramine HCl 12.5 mg

Drug Facts

Active ingredient

(in each 5 mL = 1 tsp)

Diphenhydramine HCl 12.5 mg

Purpose

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- sneezing
- runny nose
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- 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

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

- take every 4 to 6 hours
- use an accurate measuring device to administer this Medication

children under 2 years	do not use
children 2 to 5 years	ask a doctor
children 6 years to under 12 years	5 mL (1 tsp) to 10 mL (2 tsp); not more than 60 mL (12 tsp) in 24 hours
adults and children 12 years and over	10 mL (2 tsp) to 20 mL (4 tsp); not more than 120 mL (24 tsp) in 24 hours

Other information

- **each tsp contains:** sodium 5 mg
- store at 15° to 30°C (59° to 86°F)

protect from freezing

Inactive ingredients

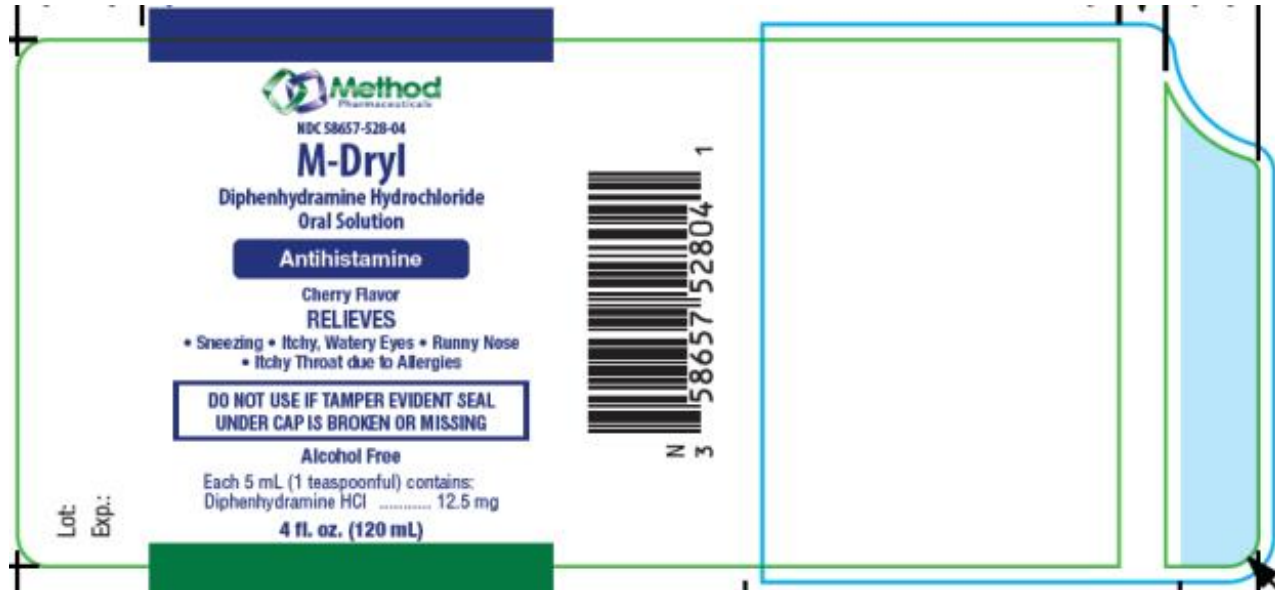
Cherry Flavor, Citric Acid Anhydrous, FD&C red No. 40, Glycerin, Masking Agent, Propylene Glycol, Purified water, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, Sorbitol Solution.

Questions?

Serious side effects associated with use of this product may be reported to this number. Call 1-877-250-3427 Mon. - Fri. (8 a.m. to 5 p.m. CST).

PRINCIPAL DISPLAY PANEL

NDC 58657-528-04
M-Dryl
Diphenhydramine Hydrochloride
Oral Solution
Antihistamine
Cherry Flavor
4 fl. oz. (120 mL)



PRINCIPAL DISPLAY PANEL

NDC 58657-528-16
M-Dryl
Diphenhydramine Hydrochloride
Oral Solution
Antihistamine
Cherry Flavor
16 fl. oz. (473 mL)

6.3750"

Drug Facts

Active ingredient **Purpose**
 (in each 5 mL = 1 tsp)
 Diphenhydramine HCl 12.5 mg

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- sneezing ■ runny nose
- itchy, watery eyes ■ itching of the nose or throat

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When using this product

- 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

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** ■ take every 4 to 6 hours
- use an accurate measuring device to administer this medication



NDC 58657-528-16

M-Dryl

Diphenhydramine Hydrochloride Oral Solution

Antihistamine

Cherry Flavor RELIEVES

- Sneezing • Itchy, Watery Eyes • Runny Nose
- Itchy Throat due to Allergies

DO NOT USE IF TAMPER EVIDENT SEAL UNDER CAP IS BROKEN OR MISSING

Alcohol Free

Each 5 mL (1 teaspoonful) contains:
 Diphenhydramine HCl 12.5 mg

16 fl. oz. (473 mL)

Drug Facts (continued)

children under 2 years	do not use
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Other information

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Inactive ingredients Cherry Flavor, Citric Acid Anhydrous, FD&C red No. 40, Glycerin, Masking Agent, Propylene Glycol, Purified water, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, Sorbitol Solution.

Questions? Comments?

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Manufactured For:
 Method Pharmaceuticals
 Fort Worth, TX 76118

Rev. 06/19



Lot:

Exp.:

M-DRYL

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58657-528
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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

SORBITOL (UNII: 506T60A25R)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-528-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2019	
2	NDC:58657-528-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	08/01/2019	

Labeler - Method Pharmaceuticals, LLC (060216698)

Revised: 8/2019

Method Pharmaceuticals, LLC