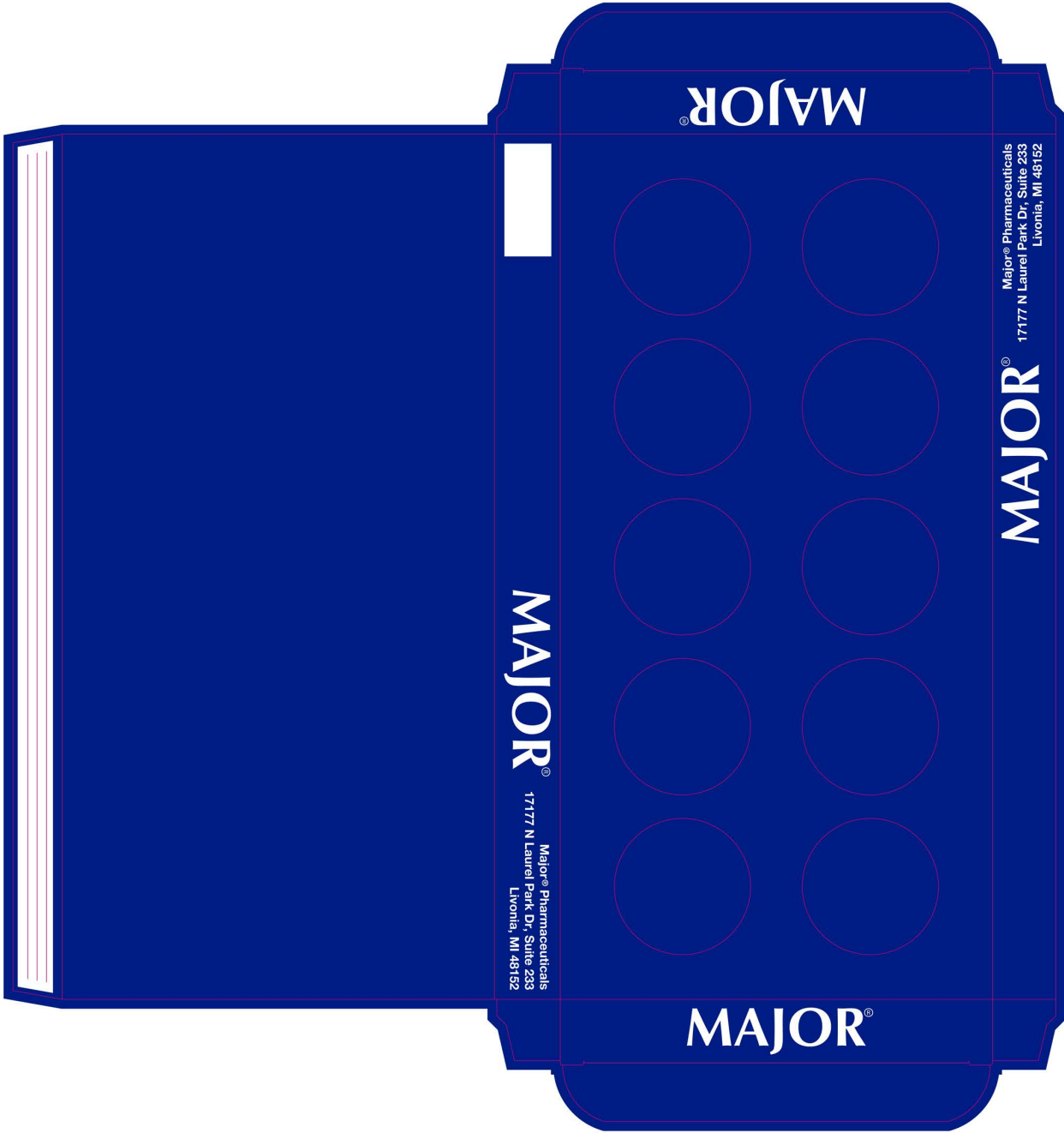


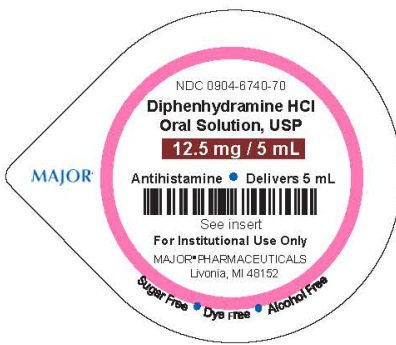
DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride liquid
Plastikon Healthcare, LLC

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.

Diphenhydramine HCl unit dose cups
Major Pharmaceuticals - For Institutional Use Only
5 mL cups 12.5 mg/ 5 mL
10 mL cups 25 mg/10 mL

Diphenhydramine HCl 12.5 mg/ 5 mL Cups





NDC 0904-6740-70

Diphenhydramine HCl

Oral Solution, USP

12.5 mg/5 mL

Antihistamine - Delivers 5 mL

See Insert

For Institutional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 64152

Sugar Free - Dye Free - Alcohol Free

Diphenhydramine HCl 12.5 mg/5 mL

Major Pharmaceuticals - IFU - Institutional Use Only

Directions

- Use the following dosage guidelines when using this product

Age (yr)

Dose (mL)

adults and children 12 years and over

take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours

children 6 years to under 12 years

take 5 mL every 4 to 6 hours; not more than 30 mL in 24 hours

children under 6 years

ask a doctor



Diphenhydramine HCl 12.5 mg/5 mL
Major Pharmaceuticals - IFU - For Institutional Use Only

Warnings

Do not use

in neonates or premature infants

if pregnant or breast-feeding

if hypersensitive to diphenhydramine HCl and other similar antihistamines
with any other product containing diphenhydramine, even one used on skin
to make a child sleepy

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if

taking tranquilizers or sedatives

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

Diphenhydramine HCl 12.5 mg/5 mL

Major Pharmaceuticals - IFU - for Institutional Use Only

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Diphenhydramine HCl 12.5 mg/5 mL

Major Pharmaceuticals - IFU - For Institutional Use Only

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itchy throat

Diphenhydramine HCl 12.5 mg/ 5 mL

Major Pharmaceutical - IFU - For Institutional Use Only

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Diphenhydramine HCl 12.5 mg/ 5 mL

Major Pharmaceuticals - IFU - For Institutional Use Only

Antihistamine

Diphenhydramine HCl 12.5 mg/ 5 mL

Major Pharmaceuticals - IFU - For Institutional Use Only

Active ingredient (in each 5 mL cup) Purpose Diphenhydramine HCl USP 12.5 mg..
.....Antihistamine

Diphenhydramine HCl 12.5 mg/5 mL
Major Pharmaceuticals - IFU - For Institutional Use Only

Other information

- each 5 mL contains: sodium 15 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Diphenhydramine HCl 12.5 mg/ 5 mL
Major Pharmaceuticals - IFU - For Institutional use Only

Product Insert
Diphenhydramine HCl Oral Solution, USP
 NDC 0904-6740-70
 10 x 5 mL Unit Dose Cups

Drug Facts

Active ingredient (in each 5 mL cup)	Purpose
Diphenhydramine HCl USP 12.5 mg.....	Antihistamine

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

Warnings

Do not use

- in neonates or premature infants
- if pregnant or breast-feeding
- if hypersensitive to diphenhydramine HCl and other similar antihistamines
- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if

- taking tranquilizers or sedatives

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

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- Use the following dosage guidelines when using this product

Age (yr)	Dose (mL)
adults and children 12 years and over	take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours
children 6 years to under 12 years	take 5 mL every 4 to 6 hours; not more than 30 mL in 24 hours
children under 6 years	ask a doctor

Other information

- each 5 mL contains: sodium 15 mg
- store at 20-25°C (68-77°F)
- do not use if lid seal is open or damaged
- see bottom of cup for lot number and expiration date
- protect from excessive moisture
- sugar free, dye free, alcohol free

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Questions or comments?

Call 1-800-616-2471

MAJOR[®]

Re-order
No. 700900

MAJOR[®] PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152

M-154
C05006 R2
Rev. 08/18

Product Insert

Diphenhydramine HCl Oral Solution, USP

NDC 0904-6740-70

10 x 5 mL Unit Dose Cups

Active ingredient (in each 5 mL cup) Purpose Diphenhydramine HCl USP 12.5 mg..
.....Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itchy throat

Warnings

Do not use

- in neonates or premature infants
- if pregnant or breast-feeding
- if hypersensitive to diphenhydramine HCl and other similar antihistamines
- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if

- taking tranquilizers or sedatives

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

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Other information

- each 5 mL contains: sodium 15 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Directions

Use the following dosage guidelines when using this product

Age (yr) Dose (mL)

adults and children 12 years and over take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours

children 6 years to under 12 years take 5 mL every 4 to 6 hours; not more than 30 mL in 24 hours

children under 6 years ask a doctor

Questions or comments?

Call 1-800-616-2471

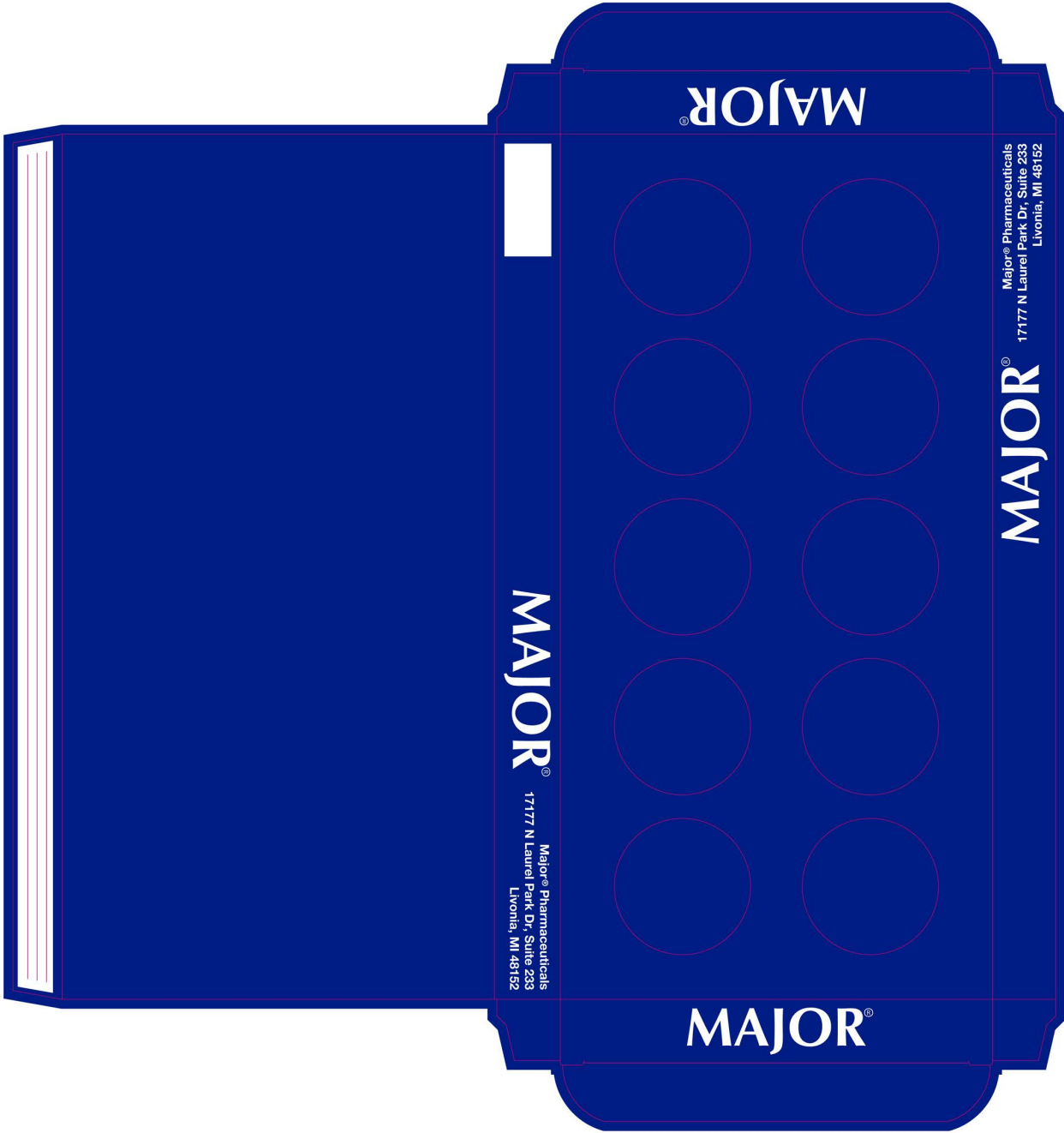
Re-order No. 700900

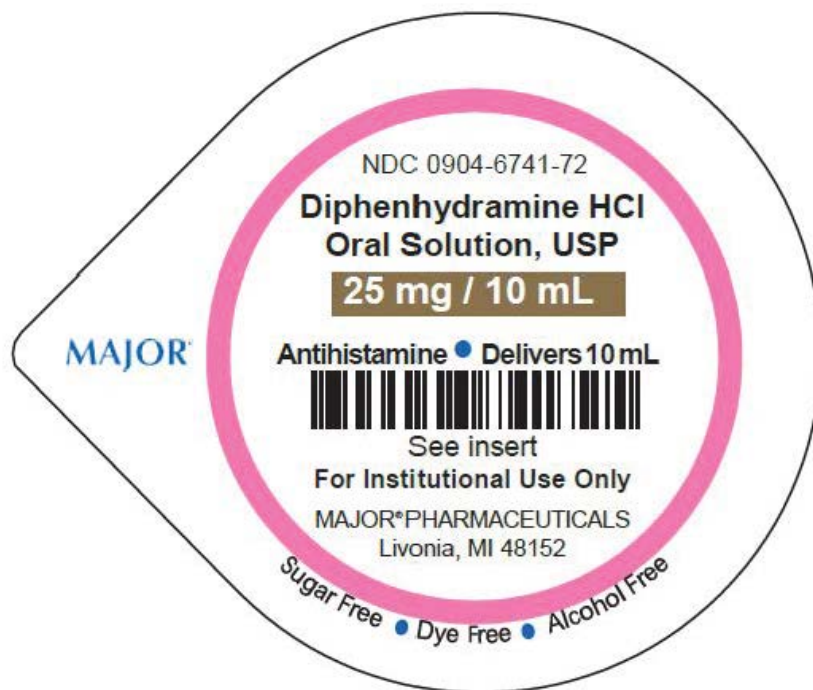
MAJOR® PHARMACEUTICALS

17177 N Laurel Park Dr., Suite 233

Livonia, MI 48152

Diphenhydramine HCl 25 mg / 10 mL Cups





NDC 0904-6741-72

Diphenhydramine HCl

Oral Solution, USP

25 mg/10 mL

Antihistamine - Delivers 10 mL

See Insert

For Institutional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 64152

Sugar Free - Dye Free - Alcohol Free

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - for Institutional use Only

Directions

Use the following dosage guidelines when using this product

Age (yr) Dose (mL)

adults and children 12 years and over take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours

children 6 years to under 12 years ask a doctor

Diphenhydramine HCl 10 mg/ 10 mL
Major Pharmaceuticals - For Institutional Use Only

Warnings

Do not use

- in neonates or premature infants
 - if pregnant or breast-feeding
 - if hypersensitive to diphenhydramine HCl and other similar antihistamines
 - with any other product containing diphenhydramine, even one used on skin
 - to make a child sleepy
-

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if

- taking tranquilizers or sedatives
-

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

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - For Institutional Use Only

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Diphenhydramine HCl 10 mg / 10 mL
Major Pharmaceuticals - For Institutional Use Only

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itchy throat

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - For Institutional use Only

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - For Institutional Use Only

Antihistamine

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - For Institutional Use Only

Active ingredient (in each 10 mL cup) Purpose Diphenhydramine HCl USP 25 mg..
.....Antihistamine

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - IFU - For Institutional Use Only

- each 10 mL contains: sodium 30 mg
 - store at 20-25°C (68-77°F)
 - protect from excessive moisture
 - do not use if lid seal is open or damaged
 - sugar free, dye free, alcohol free
 - see bottom of cup for lot number and expiration date

Diphenhydramine HCl 25 mg/ 10 mL
Major Pharmaceuticals - IFU - For Institutional Use Only

Product Insert
Diphenhydramine HCl Oral Solution, USP
 NDC 0904-6741-72
 10 x 10 mL Unit Dose Cups

Drug Facts	
Active ingredient (in each 10 mL cup)	Purpose
Diphenhydramine HCl USP 25 mg.....	Antihistamine
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itchy throat	
Warnings	
Do not use	
<ul style="list-style-type: none"> ■ in neonates or premature infants ■ if pregnant or breast-feeding ■ if hypersensitive to diphenhydramine HCl and other similar antihistamines ■ with any other product containing diphenhydramine, even one used on skin ■ to make a child sleepy 	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ a sodium restricted diet ■ trouble urinating due to an enlarged prostate gland 	
Ask a doctor or pharmacist before use if	
<ul style="list-style-type: none"> ■ taking tranquilizers or sedatives 	
When using this product	
<ul style="list-style-type: none"> ■ 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 	
Keep out of reach of children.	
In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)	
Directions	
<ul style="list-style-type: none"> ■ Use the following dosage guidelines when using this product 	
Age (yr)	Dose (mL)
adults and children 12 years and over	take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours
children 6 years to under 12 years	ask a doctor
Other information	
<ul style="list-style-type: none"> ■ each 10 mL contains: sodium 30 mg ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture ■ do not use if lid seal is open or damaged ■ sugar free, dye free, alcohol free ■ see bottom of cup for lot number and expiration date 	
Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycymthizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose	
Questions or comments?	
Call 1-800-616-2471	

Re-order
 No. 700901

MAJOR
 MAJOR® PHARMACEUTICALS
 17177 N Laurel Park Dr., Suite 233
 Livonia, MI 48152

M-154
 C05007 R 1
 Rev. 08/18

Product Insert
 Diphenhydramine HCl Oral Solution, USP

NDC 0904-6741-72

10 x 10 mL Unit Dose Cups

Active ingredient (in each 10 mL cup) Purpose Diphenhydramine HCl USP 25 mg..
.....Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itchy throat

Warnings

Do not use

- in neonates or premature infants
- if pregnant or breast-feeding
- if hypersensitive to diphenhydramine HCl and other similar antihistamines
- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if

- taking tranquilizers or sedatives

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

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

Use the following dosage guidelines when using this product

Age (yr) Dose (mL)

adults and children 12 years and over take 10 mL every 4 to 6 hours; not more than 60 mL in 24 hours

children 6 years to under 12 years ask a doctor

Other information

- each 10 mL contains: sodium 30 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free

- see bottom of cup for lot number and expiration date

Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Questions or comments?

Call 1-800-616-2471

Re-order

No. 700901

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Dr., Suite 233

Livonia, MI 48152

DIPHENHYDRAMINE HYDROCHLORIDE			
diphenhydramine hydrochloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62320-010
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)		
	AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)		
	SUCRALOSE (UNII: 96K6UQ3ZD4)		
	SODIUM CHLORIDE (UNII: 451W47IQ8X)		
	TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
	POLOXAMER 407 (UNII: TUF2IVW3M2)		
	GLYCERIN (UNII: PDC6A3C0OX)		
	SODIUM BENZOATE (UNII: OJ245FE5EU)		
	WATER (UNII: 059QF0K00R)		
Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62320-010-05	10 in 1 CASE	12/04/2018	
1		10 in 1 TRAY		
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:62320-010-10	10 in 1 CASE	12/04/2018	
2		10 in 1 TRAY		
2		10 mL in 1 CUP, UNIT-DOSE; 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	12/04/2018	

Labeler - Plastikon Healthcare, LLC (041717941)

Registrant - Plastikon Healthcare, LLC (041717941)

Establishment

Name	Address	ID/FEI	Business Operations
Plastikon Healthcare, LLC		041717941	manufacture(62320-010)

Revised: 12/2018

Plastikon Healthcare, LLC