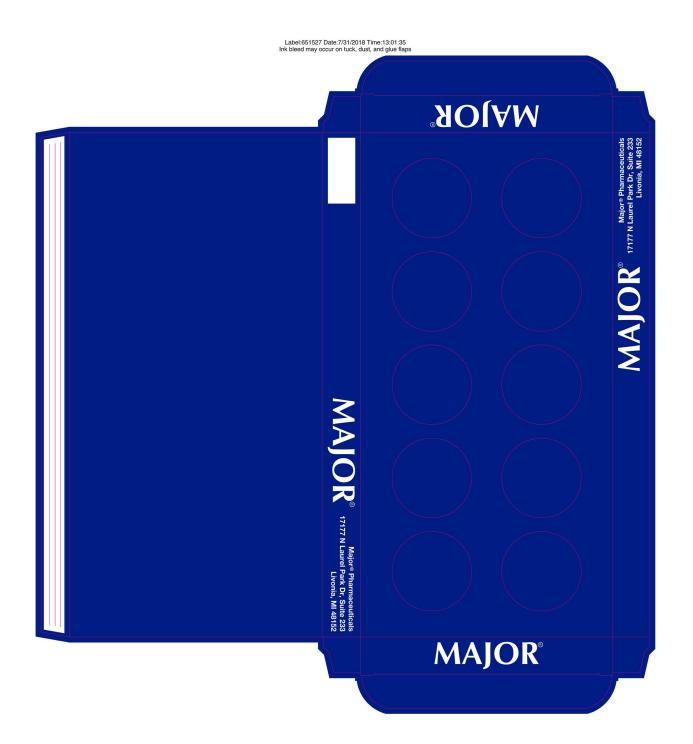
DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride liquid Plastikon Healthcare, LLC

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 Instituional 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



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

Diphenydramine 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 Intitutional Use Only

Antihistamine

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

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

Drug Facts	
Active ingredient (in	
Diphenhydramine HCI USP 1:	each 5 mL cup) Purpose 2.5 mg. Antihistamine
	nese symptoms due to hay fever or other upper nose ■ sneezing ■ itchy, watery eyes ■ itchy throa
	rou have g problem such as emphysema or chronic bronchitis I trouble urinating due to an enlarged prostate gland
 be careful when driving a m excitability may occur, espe Keep out of reach of childree 	iquilizers may increase drowsiness notor vehicle or operating machinery ecially in children
In case of overdose, get medi (1-800-222-1222)	ical help or contact a Poison Control Center right away.
Directions Use the following dosage a	uidelines 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
	 protect from excessive moisture n or damaged sugar free, dye free, alcohol free
diveventizinate poloxamer 40	r, parmed mater, social por zoare, social oriendo,
glycyrrhizinate, poloxamer 40 sodium citrate, sucralose Questions or comme	ents?

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

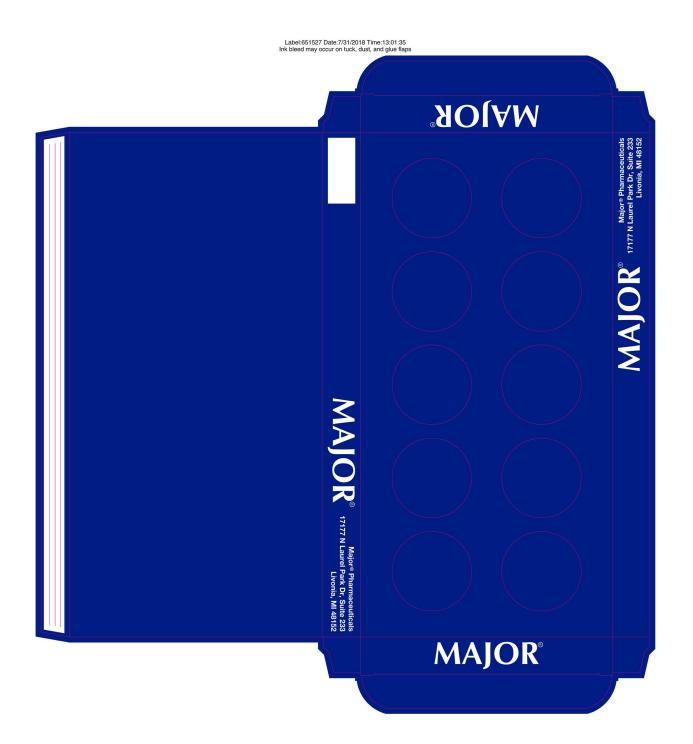
Inactive ingredients cherry flavor, citric acid, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

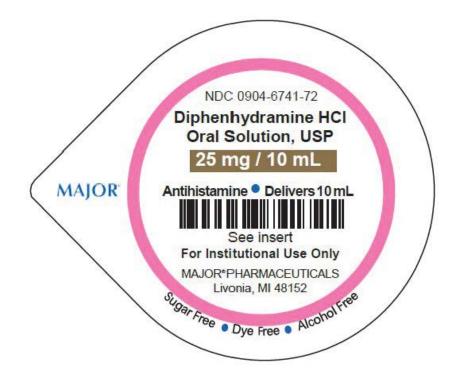
Directions

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 Instituional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 64152

Sugar Free - Dye Free - Alcohol Free

Diphenhydramine HCl 25 mg/ 10 mL Major Pharmaceuticals - for Instutional 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

Active ingredie	nt (in each 10 mL cup)	
	1 USP 25 mg	Purpose Antihistamine
	lieves these symptoms due to hay fever o ■ runny nose ■ sneezing ■ itchy, wate	
	st-feeding diphenhydramine HCI and other similar a uct containing diphenhydramine, even on	
Ask a doctor before ■ glaucoma ■ a b ■ a sodium restricted	preathing problem such as emphysema of	
Ask a doctor or phar ■ taking tranquilizers	macist before use if	
be careful when drive	anay occur avoid alcoholic drinks and tranquilizers may increase drowsines ving a motor vehicle or operating machine cur, especially in children	
 be careful when driv excitability may occ Keep out of reach of In case of overdose, g (1-800-222-1222) 	and tranquilizers may increase drowsines ving a motor vehicle or operating machine aur, especially in children	ery
 be careful when driv excitability may occ Keep out of reach of In case of overdose, g (1-800-222-1222) Directions 	and tranquilizers may increase drowsines ving a motor vehicle or operating machine rur, especially in children f children.	rol Center right away.
 be careful when driv excitability may occ Keep out of reach of In case of overdose, g (1-800-222-1222) Directions 	and tranquilizers may increase drowsines ving a motor vehicle or operating machine sur, especially in children f children. get medical help or contact a Poison Cont osage guidelines when using this product Dose (mL)	ery crol Center right away.
 be careful when driv excitability may occ Keep out of reach of In case of overdose, g (1-800-222-1222) Directions Use the following drive 	and tranquilizers may increase drowsines ving a motor vehicle or operating machine ur, especially in children f children. get medical help or contact a Poison Cont osage guidelines when using this product Dose (mL)	ery crol Center right away.
be careful when driv excitability may occ Keep out of reach of In case of overdose, g (1-800-222-122) Directions Use the following drive Age (yr) adults and children	and tranquilizers may increase drowsines ving a motor vehicle or operating machine ur, especially in children r children. get medical help or contact a Poison Cont osage guidelines when using this product Dose (mL) 12 take 10 mL every 4 to 6 hours mL in 24 hours	ery crol Center right away.
be careful when driv excitability may occ Keep out of reach of In case of overdose, con- control (1-800-222-1222) Directions Use the following drived Age (yr) adults and children years and over children 6 years to to 12 years Other informati each 10 mL contain store at 20-25°C (6) do not use if id sea see bottom of cup fi	and tranquilizers may increase drowsines ving a motor vehicle or operating machine ur, especially in children rchildren. get medical help or contact a Poison Cont osage guidelines when using this product Dose (mL) 12 take 10 mL every 4 to 6 hours mL in 24 hours under ask a doctor on s: sodium 30 mg =/77°)	rol Center right away.
 be careful when drive excitability may occ excitability may occ Keep out of reach of in case of overdose. (2) Directions Use the following drive Age (yr) adults and children years and over children 6 years to L 12 years Other informati each 10 mL contain store at 20-25°C (6) do not use if id seas see bottom of cup fi 	and tranquilizers may increase drowsines ving a motor vehicle or operating machine ur, especially in children fchildren. get medical help or contact a Poison Cont osage guidelines when using this product Dose (mL) 12 take 10 mL every 4 to 6 hours mL in 24 hours under ask a doctor on s: sodium 30 mg e-77°F)	rol Center right away.

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

Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (S	ource)	NDC:6232	20-010
Route of Administration	ORAL				
A .* T . 1* ./A .*	26 • .				
Active Ingredient/Active	•				
	Ingredient Name		Basis of Stre	ength	Strength
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE UNII:8GTS82S83M) DIPHENHYDRAMINE HYDRO CHLO RIDE			2	12.5 mg in 5 mL	
Inactive Ingredients					
	Ingredient Name			5	Strength
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)					
AMMO NIUM GLYCYRRHIZAT	E (UNII: 3VRD35U26C)				
SUCRALOSE (UNII: 96K6UQ3Z	D4)				
SODIUM CHLORIDE (UNII: 451	W47IQ8X)				
TRISO DIUM CITRATE DIHYDI					
POLOXAMER 407 (UNII: TUF2IVW3M2)					
GLYCERIN (UNII: PDC6A3C0O)					
SODIUM BENZOATE (UNII: OJ	245FE5EU)				
WATER (UNII: 059QF0KO0R)					
Product Characteristics					
		Score			
Product Characteristics Color Shape		Score Size			

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 Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
		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