## HYDRALAZINE HYDROCHLORIDE- hydralazine hydrochloride tablet, film coated

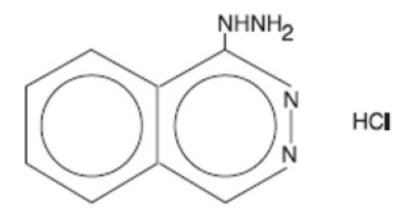
**Major Pharmaceuticals** 

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#### Rx only

#### DESCRIPTION

HydrALAZINE hydrochloride, USP, is an antihypertensive, for oral administration. Its chemical name is 1-hydrazinophthalazine monohydrochloride, and its structural formula is:



C8H8N4 • HCl M.W. 196.64

HydrALAZINE hydrochloride, USP is a white to off-white, odorless crystalline powder. It is soluble in water, slightly soluble in alcohol, and very slightly soluble in ether. It melts at about 275°C, with decomposition.

Each tablet for oral administration contains 10 mg, 25 mg, 50 mg, or 100 mg hydrALAZINE hydrochloride, USP. Tablets also contain FD&C Red #40/Allura Red AC Aluminum Lake, hypromellose, lactose anhydrous, light mineral oil, microcrystalline cellulose, magnesium stearate, pregelatinized starch, sodium lauryl sulfate, and titanium dioxide.

#### **CLINICAL PHARMACOLOGY**

Although the precise mechanism of action of hydrALAZINE is not fully understood, the major effects are on the cardiovascular system. HydrALAZINE apparently lowers blood pressure by exerting a peripheral vasodilating effect through a direct relaxation of vascular smooth muscle. HydrALAZINE, by altering cellular calcium metabolism,

interferes with the calcium movements within the vascular smooth muscle that are responsible for initiating or maintaining the contractile state.

The peripheral vasodilating effect of hydrALAZINE results in decreased arterial blood pressure (diastolic more than systolic); decreased peripheral vascular resistance; and an increased heart rate, stroke volume, and cardiac output. The preferential dilatation of arterioles, as compared to veins, minimizes postural hypotension and promotes the increase in cardiac output. HydrALAZINE usually increases renin activity in plasma, presumably as a result of increased secretion of renin by the renal juxtaglomerular cells in response to reflex sympathetic discharge. This increase in renin activity leads to the production of angiotensin II, which then causes stimulation of aldosterone and consequent sodium reabsorption. HydrALAZINE also maintains or increases renal and cerebral blood flow.

HydrALAZINE hydrochloride is rapidly absorbed after oral administration, and peak plasma levels are reached at 1 to 2 hours. Plasma levels of apparent hydrALAZINE decline with a half-life of 3 to 7 hours. Binding to human plasma protein is 87%. Plasma levels of hydrALAZINE vary widely among individuals. HydrALAZINE is subject to polymorphic acetylation; slow acetylators generally have higher plasma levels of hydrALAZINE and require lower doses to maintain control of blood pressure. HydrALAZINE undergoes extensive hepatic metabolism; it is excreted mainly in the form of metabolites in the urine.

#### INDICATIONS AND USAGE

Essential hypertension, alone or as an adjunct.

#### CONTRAINDICATIONS

Hypersensitivity to hydrALAZINE; coronary artery disease; mitral valvular rheumatic heart disease.

#### WARNINGS

In a few patients hydrALAZINE may produce a clinical picture simulating systemic lupus erythematosus including glomerulonephritis. In such patients hydrALAZINE should be discontinued unless the benefit-to-risk determination requires continued antihypertensive therapy with this drug. Symptoms and signs usually regress when the drug is discontinued but residua have been detected many years later. Long-term treatment with steroids may be necessary. (See **PRECAUTIONS, Laboratory Tests**.)

#### PRECAUTIONS

#### General

Myocardial stimulation produced by hydrALAZINE can cause anginal attacks and ECG changes of myocardial ischemia. The drug has been implicated in the production of myocardial infarction. It must, therefore, be used with caution in patients with suspected coronary artery disease.

The "hyperdynamic" circulation caused by hydrALAZINE may accentuate specific cardiovascular inadequacies. For example, hydrALAZINE may increase pulmonary artery pressure in patients with mitral valvular disease. The drug may reduce the pressor responses to epinephrine. Postural hypotension may result from hydrALAZINE but is less common than with ganglionic blocking agents. It should be used with caution in patients with cerebral vascular accidents.

In hypertensive patients with normal kidneys who are treated with hydrALAZINE, there is evidence of increased renal blood flow and a maintenance of glomerular filtration rate. In some instances where control values were below normal, improved renal function has been noted after administration of hydrALAZINE. However, as with any antihypertensive agent, hydrALAZINE should be used with caution in patients with advanced renal damage.

Peripheral neuritis, evidenced by paresthesia, numbness, and tingling, has been observed. Published evidence suggests an antipyridoxine effect, and that pyridoxine should be added to the regimen if symptoms develop.

#### Information for Patients

Patients should be informed of possible side effects and advised to take the medication regularly and continuously as directed.

### Laboratory Tests

Complete blood counts and antinuclear antibody titer determinations are indicated before and periodically during prolonged therapy with hydrALAZINE even though the patient is asymptomatic. These studies are also indicated if the patient develops arthralgia, fever, chest pain, continued malaise, or other unexplained signs or symptoms.

A positive antinuclear antibody titer requires that the physician carefully weigh the implications of the test results against the benefits to be derived from antihypertensive therapy with hydrALAZINE.

Blood dyscrasias, consisting of reduction in hemoglobin and red cell count, leukopenia, agranulocytosis, and purpura, have been reported. If such abnormalities develop, therapy should be discontinued.

## Drug /Drug Interactions

MAO inhibitors should be used with caution in patients receiving hydrALAZINE.

When other potent parenteral antihypertensive drugs, such as diazoxide, are used in combination with hydrALAZINE, patients should be continuously observed for several hours for any excessive fall in blood pressure. Profound hypotensive episodes may occur when diazoxide injection and hydrALAZINE are used concomitantly.

#### **Drug/Food Interactions**

Administration of hydrALAZINE with food results in higher plasma levels.

## Carcinogenesis, Mutagenesis, Impairment of Fertility

In a lifetime study in Swiss albino mice, there was a statistically significant increase in the incidence of lung tumors (adenomas and adenocarcinomas) of both male and female mice given hydrALAZINE continuously in their drinking water at a dosage of about 250

mg/kg per day (about 80 times the maximum recommended human dose). In a 2-year carcinogenicity study of rats given hydrALAZINE by gavage at dose levels of 15, 30, and 60 mg/kg/day (approximately 5 to 20 times the recommended human daily dosage), microscopic examination of the liver revealed a small, but statistically significant, increase in benign neoplastic nodules in male and female rats from the high-dose group and in female rats from the intermediate-dose group. Benign interstitial cell tumors of the testes were also significantly increased in male rats from the high-dose group. The tumors observed are common in aged rats and a significantly increased incidence was not observed until 18 months of treatment. HydrALAZINE was shown to be mutagenic in bacterial systems (Gene Mutation and DNA Repair) and in one of two rats and one rabbit hepatocyte *in vitro* DNA repair studies. Additional *in vivo* and *in vitro* studies using lymphoma cells, germinal cells, and fibroblasts from mice, bone marrow cells from Chinese hamsters and fibroblasts from human cell lines did not demonstrate any mutagenic potential for hydrALAZINE.

The extent to which these findings indicate a risk to man is uncertain. While long-term clinical observation has not suggested that human cancer is associated with hydrALAZINE use, epidemiologic studies have so far been insufficient to arrive at any conclusions.

### Pregnancy

### Teratogenic Effects

### Pregnancy Category C

Animal studies indicate that hydrALAZINE is teratogenic in mice at 20 to 30 times the maximum daily human dose of 200 to 300 mg and possibly in rabbits at 10 to15 times the maximum daily human dose, but that it is nonteratogenic in rats. Teratogenic effects observed were cleft palate and malformations of facial and cranial bones.

There are no adequate and well-controlled studies in pregnant women. Although clinical experience does not include any positive evidence of adverse effects on the human fetus, hydrALAZINE should be used during pregnancy only if the expected benefit justifies the potential risk to the fetus.

#### Nursing Mothers

HydrALAZINE has been shown to be excreted in breast milk.

#### Pediatric Use

Safety and effectiveness in pediatric patients have not been established in controlled clinical trials, although there is experience with the use of hydrALAZINE in pediatric patients. The usual recommended oral starting dosage is 0.75 mg/kg of body weight daily in four divided doses. Dosage may be increased gradually over the next 3 to 4 weeks to a maximum of 7.5 mg/kg or 200 mg daily.

#### **Adverse Reactions**

Adverse reactions with hydrALAZINE are usually reversible when dosage is reduced. However, in some cases it may be necessary to discontinue the drug. The following adverse reactions have been observed, but there has not been enough systematic collection of data to support an estimate of their frequency. **Common:** headache, anorexia, nausea, vomiting, diarrhea, palpitations, tachycardia, angina pectoris.

Less Frequent: Digestive: constipation, paralytic ileus.

Cardiovascular: hypotension, paradoxical pressor response, edema.

Respiratory: dyspnea.

**Neurologic:** peripheral neuritis, evidenced by paresthesia, numbness, and tingling; dizziness; tremors; muscle cramps; psychotic reactions characterized by depression, disorientation, or anxiety.

**Genitourinary:** difficulty in urination.

**Hematologic:** blood dyscrasias, consisting of reduction in hemoglobin and red cell count, leukopenia, agranulocytosis, purpura, lymphadenopathy; splenomegaly.

**Hypersensitive Reactions:** rash, urticaria, pruritus, fever, chills, arthralgia, eosinophilia, and rarely, hepatitis.

Other: nasal congestion, flushing, lacrimation, conjunctivitis.

#### To report SUSPECTED ADVERSE REACTIONS, contact Avet Pharmaceuticals Inc. at 1-866-901-DRUG (3784) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

# OVERDOSAGE

**Acute Toxicity:** No deaths due to acute poisoning have been reported. Highest known dose survived: adults, 10 g orally.

Oral LD<sub>50</sub> in rats: 173 and 187 mg/kg.

*Signs and Symptoms:* Signs and symptoms of overdosage include hypotension, tachycardia, headache, and generalized skin flushing.

Complications can include myocardial ischemia and subsequent myocardial infarction, cardiac arrhythmia, and profound shock.

**Treatment:** There is no specific antidote.

The gastric contents should be evacuated, taking adequate precautions against aspiration and for protection of the airway. An activated charcoal slurry may be instilled if conditions permit. These manipulations may have to be omitted or carried out after cardiovascular status has been stabilized, since they might precipitate cardiac arrhythmias or increase the depth of shock.

Support of the cardiovascular system is of primary importance. Shock should be treated with plasma expanders. If possible, vasopressors should not be given, but if a vasopressor is required, care should be taken not to precipitate or aggravate cardiac arrhythmia.

Tachycardia responds to beta blockers. Digitalization may be necessary, and renal function should be monitored and supported as required.

No experience has been reported with extracorporeal or peritoneal dialysis.

### **DOSAGE AND ADMINISTRATION**

Initiate therapy in gradually increasing dosages; adjust according to individual response. Start with 10 mg four times daily for the first 2 to 4 days, increase to 25 mg four times daily for the balance of the first week. For the second and subsequent weeks, increase dosage to 50 mg four times daily. For maintenance, adjust dosage to the lowest effective levels.

The incidence of toxic reactions, particularly the L.E. cell syndrome, is high in the group of patients receiving large doses of hydrALAZINE hydrochloride tablets.

In a few resistant patients, up to 300 mg of hydrALAZINE hydrochloride tablets daily may be required for a significant antihypertensive effect. In such cases, a lower dosage of hydrALAZINE hydrochloride tablets combined with a thiazide and/or reserpine or a beta blocker may be considered. However, when combining therapy, individual titration is essential to ensure the lowest possible therapeutic dose of each drug.

#### HOW SUPPLIED

HydrALAZINE Hydrochloride Tablets, USP

10 mg - round, convex, pink film-coated tablet engraved with HP above 1 on one side and plain on the other side

Carton of 100 tablets (10 tablets per blister card x 10), NDC 0904-6440-61

25 mg - round, convex, pink film-coated tablet engraved with HP above 2 on one side and plain on the other side

Carton of 100 tablets (10 tablets per blister card x 10), NDC 0904-6441-61

50 mg - round, convex, pink film-coated tablet engraved with HP above 3 on one side and plain on the other side

Carton of 100 tablets (10 tablets per blister card x 10), NDC 0904-6442-61

100 mg - round, convex, pink film-coated tablet engraved with HP above 4 on one side and plain on the other side

Carton of 100 tablets (10 tablets per blister card x 10), NDC 0904-6443-61

Bottle of 1000 tablets, NDC 0904-6443-10

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight, light-resistant container as defined in the USP. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Distributed by:

#### Avet Pharmaceuticals Inc.

East Brunswick, NJ 08816

#### Packaged and Distributed by:

#### **MAJOR® PHARMACEUTICALS**

Indianapolis, IN 46268 USA Refer to package label for Distributor's NDC Number 1-866-901-DRUG (3784)



51U00000172US06

Revised: 04/2023

## Package/Label Display Panel

hydrALAZINE HCl Tablets, USP 10 mg 100 TABLETS



## Package/Label Display Panel

hydrALAZINE HCI

Tablets, USP

25 mg



# Package/Label Display Panel

hydrALAZINE HCI

Tablets, USP

50 mg

100 TABLETS



# Package/Label Display Panel

hydrALAZINE HCl Tablets, USP 100 mg 100 TABLETS



# HYDRALAZINE HYDROCHLORIDE

hydralazine hydrochloride tablet, film coated

#### **Product Information**

HUMAN PRESCRIPTION

		DRUG	(So	urce)	001)		
Route of Admini	stration	ORAL					
Active Ingredi	ent/Acti	ive Moiety					
9		gredient Name		Bas	is of Str	enath	Strengt
<b>Hydralazine Hyd</b> JNII:26NAK24LS8)		RIDE (UNII: FD171B7	78Y) (HYDRALAZ IN	IE - HYDRA	LAZ INE CHLORIDE	<b>-</b>	10 mg
Inactive Ingre	dients						
		Ingredien	t Name			St	rength
FD&C RED NO. 40	ALUMINU	M LAKE (UNII: 6T47					
HYPROMELLOSE, U	UNSPECIF	IED (UNII: 3NXW29V3	3WO)				
ANHYDROUS LACT	OSE (UNII:	3SY5LH9PMK)					
LIGHT MINERAL OI	IL (UNII: N6	K5787QVP)					
MICROCRYSTALLIN	NE CELLUI	OSE (UNII: OP1R32	D61U)				
MAGNESIUM STEA	RATE (UNI	I: 70097M6I30)					
STARCH, CORN (UI	NII: 08232N	NY3SJ)					
SODIUM LAURYL S	ULFATE (l	JNII: 368GB5141J)					
Product Chara	acteristi	cs	Coordina				
Product Chara Color	acteristi	<b>CS</b> PINK	Score			o score	
<b>Product Chara</b> Color Shape	acteristi	cs	Size		7n	nm	
<b>Product Chara</b> Color Shape Flavor	acteristi	<b>CS</b> PINK			7n		
<b>Product Chara</b> Color Shape Flavor	acteristi	<b>CS</b> PINK	Size		7n	nm	
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Product Chara Color Shape Flavor Contains Packaging # Item Code 1 NDC:0904-6440- 61	100 in 1 C.	CS PINK ROUND Package Desci	Size Imprint Code	<b>Date</b> 05/14/2015	Start	nm 2;1 Market D	ate
Product Chara Color Shape Flavor Contains Packaging Item Code 1 NDC:0904-6440- 61	100 in 1 C. 1 in 1 BLIS Product	CS PINK ROUND Package Descu ARTON STER PACK; Type 0: 1	Size Imprint Code	<b>Date</b> 05/14/2015	Start	nm 2;1 Market D	ate
Product Chara Color Shape Flavor Contains Packaging Item Code 1 NDC:0904-6440- 61	100 in 1 C. 1 in 1 BLIS Product	CS PINK ROUND Package Descu ARTON STER PACK; Type 0: 1	Size Imprint Code	<b>Date</b> 05/14/2015	Start	nm 2;1 Market D	ate
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# HYDRALAZINE HYDROCHLORIDE

hydralazine hydrochloride tablet, film coated

	mation						
Product Type	DRUG (Sou			ltem Code (Source)	ND0 002		441(NDC:23155-
Route of Admin	istration	ORAL					
Active Ingred	ient/Acti	ive Moiety					
	In	gredient Name			Basis of	f Stren	gth Streng
<b>Hydralazine Hyi</b> Unii:26NAK24LS8)	DROCHLOF	RIDE (UNII: FD171B77	'8Y) (HYDRAL/	AZINE -	HYDRALAZ IN HYDROCHLC		25 mg
Inactive Ingre	edients						
		Ingredient	Name				Strength
		M LAKE (UNII: 6T47A	· · · · ·				
-		IED (UNII: 3NXW29V3	WO)				
ANHYDROUS LACT							
LIGHT MINERAL O							
		OSE (UNII: OP1R32D	010)				
		1221					
		-					
SODIUM LAURYL S	SULFATE (L	JNII: 368GB5141J)					
SODIUM LAURYL S	SULFATE (L	JNII: 368GB5141J)					
SODIUM LAURYL S TITANIUM DIOXID	SULFATE (U E (UNII: 15F	JNII: 368GB5141J) IX9V2JP)					
SODIUM LAURYL S TITANIUM DIOXID Product Chara	SULFATE (U E (UNII: 15F	JNII: 368GB5141J) IX9V2JP)	Score			no sc	core
SODIUM LAURYL S TITANIUM DIOXID <b>Product Char</b> a Color	SULFATE (U E (UNII: 15F	JNII: 368GB5141J) IX9V2JP)	Score Size			no sc 8mm	
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SODIUM LAURYL S TITANIUM DIOXID Product Chara Color Shape Flavor	SULFATE (U E (UNII: 15F	JNII: 368GB5141J) FIX9V2JP) CS PINK	Size	de		8mm	
SODIUM LAURYL S TITANIUM DIOXID Product Chara Color Shape Flavor Contains	SULFATE (U E (UNII: 15F	JNII: 368GB5141J) FIX9V2JP) CS PINK	Size			8mm HP;2	
SODIUM LAURYL S TITANIUM DIOXID Product Chara Color Shape Flavor Contains Packaging	SULFATE (U E (UNII: 15F	JNII: 368GB5141J) FIX9V2JP) CS PINK	Size Imprint Co		eting Star Date	8mm HP;2	
SODIUM LAURYL S TITANIUM DIOXID Product Chara Color Shape Flavor Contains Packaging # Item Code	SULFATE (U E (UNII: 15F	JNII: 368GB5141J) IX9V2JP) CS PINK ROUND Package Descr	Size Imprint Co		Date	8mm HP;2	arketing End
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# HYDRALAZINE HYDROCHLORIDE

Product Infor	mation							
Product Type		HUMAN PRESCE DRUG	RIPTION	ltem Co (Source		NDC:0904-6442( 003)	4-6442(NDC:23155-	
Route of Admin	istration	ORAL						
Active Ingred	ient/Active	Moiety						
	Ingre	edient Name			Basi	is of Strength	Strength	
<b>Hydralazine Hyi</b> Unii:26NAK24LS8)	DROCHLORIDE	E (UNII: FD171B77	78Y) (HYDRAL	AZINE -	HYDRAL HYDRO(	AZ INE CHLORIDE	50 mg	
Inactive Ingre	edients							
		Ingredient				S	strength	
FD&C RED NO. 40		•	•					
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MICROCRYSTALLI			061U)					
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Product Chara	acteristics	,, ,						
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Color Shape	PIN		Score Size			10mm		
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Color Shape Flavor	PIN	ĸ	Size	ode		10mm		
Color Shape Flavor Contains	PIN	ĸ	Size			10mm HP;3		
Color Shape Flavor Contains <b>Packaging</b>	PIN RO	ĸ	Size Imprint Co		1arketing Date	10mm HP;3 Start Mark	eting End Date	
Color Shape Flavor Contains Packaging # Item Code	PIN RO Pa	K UND	Size Imprint Co	M		10mm HP;3 Start Mark	Date	
Color Shape Flavor Contains Packaging # Item Code 1 NDC:0904-6442- 61	PIN RO PIN RO 100 in 1 CART	K UND	Size Imprint Co	05/	Date	10mm HP;3 Start Mark	Date	
Color Shape Flavor Contains Packaging # Item Code 1 NDC:0904-6442- 61	PIN RO 100 in 1 CART 1 in 1 BLISTEF Product	K UND Ackage Descr ON & PACK; Type 0: N	Size Imprint Co	05/	Date	10mm HP;3 Start Mark	Date	
Shape Flavor Contains Packaging # Item Code 1 NDC:0904-6442- 61 1 Marketing Marketing	PIN RO Pa 100 in 1 CART 1 in 1 BLISTER Product	K UND Ackage Descr ON R PACK; Type 0: N Cion	Size Imprint Co iption lot a Combin	05/ nation	Date 14/2015 Marketing	10mm HP;3 Start Mark 02/28/20	Date 125 seting End	
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Product Information           Product Type         HUMAN PRESCRIPTION DRUG         Item Code (Source)           Route of Administration         ORAL           ORAL           Active Ingredient/Active Moiety           Ingredient Name           HYDRALAZINE HYDROCHLORIDE (UNII: FD171B778Y) (HYDRALAZINE + UNII:26NAK24LS8)           Ingredients           FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47A5764T)           HYPROMELLOSE, UNSPECIFIED (UNII: 3NXX029V3WO)           ANHYDROUS LACTOSE (UNII: 3SYSLH9PMK)           LIGHT MINERAL OIL (UNII: 3SYSLH9PMK)           INGROCRYSTALLINE CELLULOSE (UNII: 0097M6I30)           STARCH, CORN (UNII: 08232NY35)           STARCH, CORN (UNII: 08232NY35)           STARCH, CORN (UNII: 15FIX9v2JP)           PINK         Score           Shape         ROUND         Size           Flavor         Imprint Colspan="2"           PINK         Score           Size           PINK         Score           Size           Size <t< th=""><th></th><th></th><th></th></t<>						
Product iype       DRUG       (Source)         Route of Administration       ORAL       ORAL       Active Ingredient/Active Moiety       Ingredient Name         Active Ingredient/Active Ingredient Name       Ingredient Name       Ingredient Name       Ingredient Name         HYDRALAZINE HYDROCHLORIDE (UNII: FD171B778Y) (HYDRALAZINE - UNII:26NAK24L58)       Ingredient Name       Ingredient Name         FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6147A5764T)       Ingredient Name       Ingredient Name         FD&C RED NO. 40 ALUMINUM LAKE (UNII: 3NXW29V3WO)       ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)       Ingredient Name         IIGHT MINERAL OIL (UNII: N6K5787QVP)       MICROCRYSTALLINE CELLULOSE (UNII: 0091R32D61U)       MAGNESIUM STEARATE (UNII: 70097M6130)         STARCH, CORN (UNII: 08232NY35J)       SODIUM LAURYL SULFATE (UNII: 368GB5141J)       Ingrint Code         Starch, CORN (UNII: 15FIX9V2JP)       Ingrint Code       Size         Product Characteristics       Size       Ingrint Code         Flavor       Size       Ingrint Code       Size         Flavor       Ingredient Size       Ingrint Code       Size         In NDC:0904-6443       1000 in 1 BOTTLE; Type 0: Not a Combination       05/14/2         2       NDC:0904-6443       100 in 1 CARTON       05/14/2         2       NDC:0904-6443       100 in 1 CAR						
Active Ingredient/Active Moiety Ingredient Name HYDRALAZINE HYDROCHLORIDE (UNII: FD171B778Y) (HYDRALAZINE - UNII:26NAK24L58) Inactive Ingredients Ingredient Name FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47A5764T) HYPROMELLOSE, UNSPECIFIED (UNII: 3NX029V3WO) ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) LIGHT MINERAL OIL (UNII: 3SY5LH9PMK) LIGHT MINERAL OIL (UNII: 3065787QVP) MICROCRYSTALLINE CELLULOSE (UNII: 0P1R32D61U) MAGNESIUM STEARATE (UNII: 70097M6I30) STARCH, CORN (UNII: 08232NY3SJ) SODIUM LAURYL SULFATE (UNII: 368GB5141J)) TITANIUM DIOXIDE (UNII: 15FIX9V2JP)  Product Characteristics Color PINK Score Shape ROUND Size Flavor PINK Size Havor Size Flavor PINK Size Flavor MOUND Size ROUND Size Flavor MINE Size MATE MOUND Size MATE MATE MOUND Size MATE MATE MOUND SIZE MATE MATE MOUND SIZE MATE MATE MATE MATE MATE MATE MATE MAT						
Ingredient Name         HYDRALAZINE HYDROCHLORIDE (UNII: FD171B778Y) (HYDRALAZINE - UNII:26NAK24L58)         Ingredient Name         Ingredient Name         FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)         HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)         ANHYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)         ANHYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)         ANHYPROMELLOSE (UNII: 3SYSLH9PMK)         LIGHT MINERAL OIL (UNII: N6K5787QVP)         MICROCRYSTALLINE CELLULOSE (UNII: 0P1R32D61U)         MAGNESIUM STEARATE (UNII: 70097M6130)         STARCH, CORN (UNII: 08232NY35J)         SODIUM LAURYL SULFATE (UNII: 368GB5141J)         ITTANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         Color         PINK         Size         Flavor         Imprint Code         Contains         Packaging         #         Marf         NDC:0904-6443-         1000 in 1 BOTTLE; Type 0: Not a Combination         Product						
HYDRALAZINE HYDROCHLORIDE (UNII: FD171B778Y) (HYDRALAZINE - UNII:26NAK24LS8) Inactive Ingredients FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T) HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) LIGHT MINERAL OIL (UNII: N6K5787QVP) MICROCRYSTALLINE CELLULOSE (UNII: 0P1R32D61U) MAGNESIUM STEARATE (UNII: 70097M6130) STARCH, CORN (UNII: 08232NY3SJ) SODIUM LAURYL SULFATE (UNII: 368GB5141J) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Product Characteristics Color PINK Score Shape ROUND Size Flavor Imprint Code Contains PINK Score Shape MOUND Size Flavor MIDE (UNII: 15FIX9V2JP) Proteckaging # teem Code Package Description Mark 1000 in 1 BOTTLE; Type 0: Not a Combination 05/14/2 2 NDC:0904-6443- 1000 in 1 CARTON 05/14/2 1 in 1 BLISTER PACK; Type 0: Not a Combination 05/14/2 2 NDC:0904-6443- 100 in 1 CARTON 05/14/2						
Inactive Ingredients Ingredient Name FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T) HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK) LIGHT MINERAL OIL (UNII: N6K5787QVP) MICROCRYSTALLINE CELLULOSE (UNII: 0P1R32D61U) MAGNESIUM STEARATE (UNII: 70097M6130) STARCH, CORN (UNII: 08232NY3SJ) SODIUM LAURYL SULFATE (UNII: 368GB5141J) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Product Characteristics Color PINK Score Shape ROUND Size Flavor PINK Score Shape ROUND Size Flavor PINK Score Shape MOUND Size Flavor PINK Score Shape POUD Size Flavor MINI: 15FIX9V2JP) Product Characteristics Color PINK Score Shape MOUND Size Flavor MINI: 15FIX9V2JP) Product Characteristic Imprint Code Contains I 000 in 1 BOTTLE; Type 0: Not a Combination 05/14/2 NDC:0904-6443- 1000 in 1 CARTON 05/14/2 NDC:0904-6443- 100 II CARTON 05/14/2 NDC:0904-6443- 100 II CARTON 05/	Basis of St	rength	Strengt			
Ingredient Name         FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)         HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)         ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)         LIGHT MINERAL OIL (UNII: N6K5787QVP)         MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)         MAGNESIUM STEARATE (UNII: 70097M6I30)         STARCH, CORN (UNII: 08232NY3SJ)         SODIUM LAURYL SULFATE (UNII: 368GB5141J)         TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         Color         PINK         Size         Flavor         Imprint Code         Contains         Packaging         # Item Code       Package Description       Mari         1000 in 1 BOTTLE; Type 0: Not a Combination product       05/14/2         NDC:0904-6443-       100 in 1 CARTON       05/14/2         ACOMIC in 1 BUSTER PACK; Type 0: Not a Combination	YDRALAZINE HYDROCHLORIDE (UNII: FD171B778Y) (HYDRALAZINE - HYDRALAZINE					
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)         HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)         ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)         LIGHT MINERAL OIL (UNII: N6K5787QVP)         MICROCRYSTALLINE CELLULOSE (UNII: 0P1R32D61U)         MAGNESIUM STEARATE (UNII: 70097M6130)         STARCH, CORN (UNII: 08232NY3SJ)         SODIUM LAURYL SULFATE (UNII: 368GB5141J)         TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         Color       PINK       Score         Shape       ROUND       Size         Flavor       Imprint Code       PINK         Color       PINK         Magnesium Stearate (UNII: 15FIX9V2JP)         Product Characteristics         Color         PINK       Size         Packaging         Magnesity         Magnesity         Motion 1 BOTTLE; Type 0: Not a Combination product         NDC:0904-6443-         100 in 1 CARTON       05/14/2         2       NDC:0904-6443-       100 in 1 CARTON       05/14/2         2       NDC:0904-6443-       100 in 1 CARTON       05/14/2						
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)         ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)         LIGHT MINERAL OIL (UNII: N6K5787QVP)         MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)         MAGNESIUM STEARATE (UNII: 70097M6130)         STARCH, CORN (UNII: 08232NY3SJ)         SODIUM LAURYL SULFATE (UNII: 368GB5141J)         TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         Color       PINK         Shape       ROUND         Flavor       Imprint Code         Contains       Imprint Code         Markage Description         Markage Description       05/14/2         1       NDC:0904-6443- 61       100 in 1 CARTON       05/14/2         2       NDC:0904-6443- 61       100 in 1 CARTON       05/14/2		St	rength			
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)         LIGHT MINERAL OIL (UNII: N6K5787QVP)         MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)         MAGNESIUM STEARATE (UNII: 70097M6130)         STARCH, CORN (UNII: 08232NY3SJ)         SODIUM LAURYL SULFATE (UNII: 368GB5141J)         TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         Color         PINK       Score         Shape       ROUND       Size         Flavor         Imprint Code         Color       PINK         Stare flavor         Color         Package Description         Marl         1       NDC:0904-6443-       1000 in 1 BOTTLE; Type 0: Not a Combination Product       05/14/2         2       NDC:0904-6443-       100 in 1 CARTON       05/14/2         2       NDC:0904-6443-       100 in 1 BLISTER PACK; Type 0: Not a Combination       05/14/2						
IIGHT MINERAL OIL (UNII: N6K5787QVP)         MAGNESIUM STEARATE (UNII: 70097M6130)         STARCH, CORN (UNII: 08232N735J)         STARCH, CORN (UNII: 08232N735J)         SOTIUM LAURYL SULFATE (UNII: 368GB5141J)         TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         Socium Colspan="2">PINK         Score         PINK         Size         Imprint Code         Size         Flavor         Contains         Package Description         Maria         1000 in 1 BOTTLE; Type 0: Not a Combination product         Product Characteristics						
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)         MAGNESIUM STEARATE (UNII: 70097M6I30)         STARCH, CORN (UNII: 08232NY3SJ)         SODIUM LAURYL SULFATE (UNII: 368GB5141J)         TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         Color       PINK         Score         Shape       ROUND         Flavor       ROUND         Contains         Stare Vertice V						
MAGNESIUM STEARATE (UNII: 70097M6I30)         STARCH, CORN (UNII: 08232NY3SJ)         SODIUM LAURYL SULFATE (UNII: 368GB5141J)         TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         Color         PINK       Score         Shape         Flavor       ROUND         Contains         Size         Imprint Code         Contains         Package Description         Mark       Mark         1       NDC:0904-6443- 10       100 in 1 BOTTLE; Type 0: Not a Combination product       05/14/2         2       NDC:0904-6443- 61       100 in 1 CARTON       05/14/2         2       NDC:0904-6443- 61       100 in 1 CARTON       05/14/2						
STARCH, CORN (UNII: 08232NY3SJ) SODIUM LAURYL SULFATE (UNII: 368GB5141J) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Product Characteristics Color PINK Score Shape ROUND Size Flavor ROUND Size Flavor Instruction Market South Struction Market Flavor Instruction Market Market 1 NDC:0904-6443- 10 NDC:0904-6443- 1						
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)         Product Characteristics         Color       PINK       Score         Shape       ROUND       Size         Imprint Code         Flavor       Imprint Code         Contains       Mark         Package Description       Mark         Mark         Motion 1 BOTTLE; Type 0: Not a Combination       05/14/2         NDC:0904-6443-       100 in 1 CARTON       Contains       05/14/2         2       In 1 BLISTER PACK; Type 0: Not a Combination						
PINK       Score         Shape       ROUND       Size         Imprint Code         Flavor       Imprint Code         Contains       Imprint Code         Package Description       Mark         #       Item Code       Package Description       Mark         1       NDC:0904-6443:       1000 in 1 BOTTLE; Type 0: Not a Combination Product       05/14/2         2       NDC:0904-6443:       100 in 1 CARTON       05/14/2						
Color       PINK       Score         Shape       ROUND       Size         Flavor       Imprint Code         otations       Imprint Code         Vortains       Vortains         Vortains       Imprint Code         Vortains       Vortains         Vortains       Imprint Code         Vortains       Vortains         Vortains       Imprint Code         Vortains						
Color       PINK       Score         Shape       ROUND       Size         Flavor       Imprint Code         otations       Imprint Code         Vortains       Vortains         Vortains       Imprint Code         Vortains       Vortains         Vortains       Imprint Code         Vortains       Vortains         Vortains       Imprint Code         Vortains						
Color       PINK       Score         Shape       ROUND       Size         Flavor       Imprint Code         contains       Imprint Code         V       Package Description         Mark         1       NDC:0904-6443 10       100 in 1 BOTTLE; Type 0: Not a Combination Product       05/14/2         2       NDC:0904-6443       100 in 1 CARTON       05/14/2						
Shape         ROUND         Size           Flavor         Imprint Code           Contains         Imprint Code           Packaging         Mark           Item Code         Package Description         Mark           1         NDC:0904-6443- 10         1000 in 1 BOTTLE; Type 0: Not a Combination Product         05/14/2           2         NDC:0904-6443- 61         100 in 1 CARTON         05/14/2           2         In 1 BLISTER PACK; Type 0: Not a Combination         05/14/2	n	no score				
Flavor       Imprint Code         Contains       Imprint Code         Packaging       Mark         #       Item Code       Package Description       Mark         1       NDC:0904-6443- 10       1000 in 1 BOTTLE; Type 0: Not a Combination Product       05/14/2         2       NDC:0904-6443- 61       100 in 1 CARTON       05/14/2         2       NDC:0904-6443- 61       100 in 1 CARTON       05/14/2		11mm				
Package Description       Mark         Item Code       Package Description         NDC:0904-6443       1000 in 1 BOTTLE; Type 0: Not a Combination         NDC:0904-6443       000 in 1 CARTON         NDC:0904-6443       100 in 1 CARTON         In 1 BLISTER PACK; Type 0: Not a Combination       05/14/2		1P;4				
Packaging         #       Item Code       Package Description       Mark         1       NDC:0904-6443- 10       1000 in 1 BOTTLE; Type 0: Not a Combination Product       05/14/2         2       NDC:0904-6443- 61       100 in 1 CARTON       05/14/2         2       In 1 BLISTER PACK; Type 0: Not a Combination       05/14/2	•	,-				
#Item CodePackage DescriptionMark1NDC:0904-6443- 101000 in 1 BOTTLE; Type 0: Not a Combination Product05/14/22NDC:0904-6443- 61100 in 1 CARTON05/14/221 in 1 BLISTER PACK; Type 0: Not a Combination05/14/2						
<b>1</b> NDC:0904-6443- 10       1000 in 1 BOTTLE; Type 0: Not a Combination Product       05/14/2 <b>2</b> NDC:0904-6443- 61       100 in 1 CARTON       05/14/2 <b>2</b> In 1 BLISTER PACK; Type 0: Not a Combination       05/14/2						
10       Product       05/14/2         2       NDC:0904-6443- 61       100 in 1 CARTON       05/14/2         2       1 in 1 BLISTER PACK; Type 0: Not a Combination       05/14/2	keting Start Date		ting End ate			
61     100 III 1 CARTON     03/14/2       1 in 1 BLISTER PACK; Type 0: Not a Combination	2015	05/14/201	5			
	2015	02/28/202	:5			
Marketing Information						

Category	Citation	Date	Date
ANDA	ANDA086242	05/14/2015	02/28/2025

# Labeler - Major Pharmaceuticals (191427277)

Revised: 6/2024

Major Pharmaceuticals