VERAPAMIL HYDROCHLORIDE- verapamil hydrochloride injection
Areva Pharmaceuticals

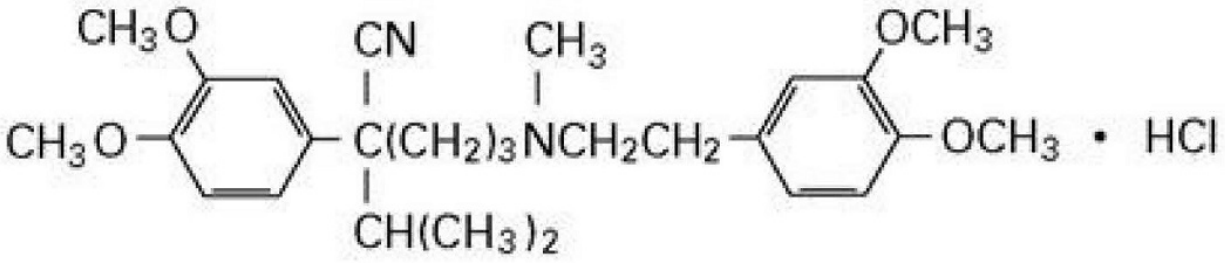
Verapamil
Hydrochloride Injection, USP

For Intravenous Injection

DESCRIPTION

Verapamil hydrochloride injection is a calcium antagonist or slow-channel inhibitor. Verapamil hydrochloride injection is available in 5 mg/2 mL and 10 mg/4 mL single dose vials (for intravenous administration). Each 1 mL of solution contains 2.5 mg verapamil HCl and 8.5 mg sodium chloride in water for injection. Hydrochloric acid is used for pH adjustment. The pH of the solution is between 4 to 6.5. Protect contents from light. Verapamil hydrochloride injection, vials are sterile.

The structural formula of verapamil hydrochloride is given below:



C27H38N2O4 • HCl M.W. = 491.06

Benzeneacetonitrile, α-[3-[{2-(3,4-dimethoxyphenyl)ethyl} methylamino] propyl]-

3,4-dimethoxy-α-(1-methylethyl) hydrochloride

Verapamil hydrochloride is an almost white crystalline powder, practically free of odor, with a bitter taste. It is soluble in water, chloroform and methanol. Verapamil hydrochloride is not chemically related to other antiarrhythmic drugs.

CLINICAL PHARMACOLOGY

Mechanism of Action

Verapamil hydrochloride injection inhibits the calcium ion (and possibly sodium ion) influx through slow channels into conductile and contractile myocardial cells and vascular

smooth muscle cells. The antiarrhythmic effect of verapamil hydrochloride injection appears to be due to its effect on the slow channel in cells of the cardiac conduction system. The vasodilatory effect of verapamil hydrochloride injection appears to be due to its effect on blockade of calcium channels as well as α receptors.

In the isolated rabbit heart, concentrations of verapamil hydrochloride injection that markedly affect SA nodal fibers or fibers in the upper and middle regions of the AV node have very little effect on fibers in the lower AV node (NH region) and no effect on atrial action potentials or His bundle fibers.

Electrical activity in the SA and AV nodes depends, to a large degree, upon calcium influx through the slow channel. By inhibiting this influx, verapamil hydrochloride injection slows AV conduction and prolongs the effective refractory period within the AV node in a rate-related manner. This effect results in a reduction of the ventricular rate in patients with atrial flutter and/or atrial fibrillation and a rapid ventricular response.

By interrupting reentry at the AV node, verapamil hydrochloride injection can restore normal sinus rhythm in patients with paroxysmal supraventricular tachycardias (PSVT), including PSVT associated with Wolff-Parkinson-White syndrome.

Verapamil hydrochloride injection does not induce peripheral arterial spasm.

Verapamil hydrochloride injection has a local anesthetic action that is 1.6 times that of procaine on an equimolar basis. It is not known whether this action is important at the doses used in man.

Verapamil hydrochloride injection does not alter total serum calcium levels.

Hemodynamics

Verapamil hydrochloride injection reduces afterload and myocardial contractility. The commonly used intravenous doses of 5 to 10 mg verapamil hydrochloride injection produce transient, usually asymptomatic, reduction in normal systemic arterial pressure, systemic vascular resistance and contractility; left ventricular filling pressure is slightly increased. In most patients, including those with organic cardiac disease, the negative inotropic action of verapamil hydrochloride injection is countered by reduction of afterload, and cardiac index is usually not reduced. However, in patients with moderately severe to severe cardiac dysfunction (pulmonary wedge pressure above 20 mm Hg, ejection fraction less than 30%), acute worsening of heart failure may be seen. Peak therapeutic effects occur within 3 to 5 minutes after a bolus injection.

Pharmacokinetics

Intravenously administered verapamil hydrochloride injection has been shown to be rapidly metabolized. Following intravenous infusion in man, verapamil is eliminated bi-exponentially, with a rapid early distribution phase (half-life about 4 minutes) and a slower terminal elimination phase (half-life 2 to 5 hours). In healthy men, orally administered verapamil hydrochloride injection undergoes extensive metabolism in the liver, 12 metabolites having been identified, most in only trace amounts. The major metabolites have been identified as various N- and O- dealkylated products of verapamil hydrochloride injection. Approximately 70% of an administered dose is excreted in the urine and 16% or more in the feces within 5 days. About 3% to 4% is excreted as unchanged drug.

Aging may affect the pharmacokinetics of verapamil given to hypertensive patients. Elimination half-life may be prolonged in the elderly.

INDICATIONS AND USAGE

Intravenous verapamil hydrochloride injection is indicated for the following:

- Rapid conversion to sinus rhythm of paroxysmal supraventricular tachycardias, including those associated with accessory bypass tracts (Wolff-Parkinson-White [W-P-W] and Lown-Ganong-Levine [L-G-L] syndromes). When clinically advisable, appropriate vagal maneuvers (e.g., Valsalva maneuver) should be attempted prior to verapamil hydrochloride injection administration.
- Temporary control of rapid ventricular rate in atrial flutter or atrial fibrillation except when the atrial flutter and/or atrial fibrillation are associated with accessory bypass tracts (Wolff-Parkinson-White (W-P-W) and Lown-Ganong-Levine (L-G-L) syndromes).

In controlled studies in the United States, about 60% of patients with supraventricular tachycardia converted to normal sinus rhythm within 10 minutes after intravenous verapamil hydrochloride injection. Uncontrolled studies reported in the world literature describe a conversion rate of about 80%. About 70% of patients with atrial flutter and/or fibrillation with a fast ventricular rate respond with a decrease in ventricular rate of at least 20%. Conversion of atrial flutter or fibrillation to sinus rhythm is uncommon (about 10%) after verapamil hydrochloride injection and may reflect the spontaneous conversion rate, since the conversion rate after placebo was similar. Slowing of the ventricular rate in patients with atrial fibrillation/flutter lasts 30 to 60 minutes after a single injection.

Because a small fraction (<1%) of patients treated with verapamil hydrochloride injection respond with life-threatening adverse responses (rapid ventricular rate in atrial flutter/fibrillation, and an accessory bypass tract, marked hypotension, or extreme bradycardia/asystole – see *CONTRAINDICATIONS* and *WARNINGS*), the initial use of intravenous verapamil hydrochloride injection should, if possible, be in a treatment setting with monitoring and resuscitation facilities, including DC-cardioversion capability (see *ADVERSE REACTIONS:Suggested Treatment of Acute Cardiovascular Adverse Reactions*). As familiarity with the patient's response is gained, use in an office setting may be acceptable .

Cardioversion has been used safely and effectively after verapamil hydrochloride injection.

CONTRAINDICATIONS

Intravenous verapamil hydrochloride injection is contraindicated in:

1. Severe hypotension or cardiogenic shock.
2. Second- or third-degree AV block (except in patients with a functioning artificial ventricular pacemaker).
3. Sick sinus syndrome (except in patients with a functioning artificial ventricular pacemaker).
4. Severe congestive heart failure (unless secondary to a supraventricular tachycardia

amenable to verapamil therapy).
5. Patients receiving **intravenous** beta-adrenergic blocking drugs (e.g., propranolol). **Intravenous** verapamil and **intravenous** beta-adrenergic blocking drugs should not be administered in close proximity to each other (within a few hours), since both may have a depressant effect on myocardial contractility and AV conduction.
6. Patients with atrial flutter or atrial fibrillation and an accessory bypass tract (e.g., Wolff-Parkinson-White, Lown-Ganong-Levine syndromes) are at risk to develop ventricular tachyarrhythmia including ventricular fibrillation if verapamil is administered. Therefore, the use of verapamil in these patients is contraindicated.
7. Ventricular Tachycardia. Administration of intravenous verapamil to patients with wide-complex ventricular tachycardia (QRS ≥ 0.12 sec) can result in marked hemodynamic deterioration and ventricular fibrillation. Proper pre-therapy diagnosis and differentiation from wide-complex supraventricular tachycardia is imperative in the emergency room setting.
8. Known hypersensitivity to verapamil hydrochloride.

WARNINGS

VERAPAMIL HYDROCHLORIDE INJECTION SHOULD BE GIVEN AS A SLOW INTRAVENOUS INJECTION OVER AT LEAST A TWO MINUTE PERIOD OF TIME (see *DOSAGEAND ADMINISTRATION*).

Hypotension

Intravenous verapamil hydrochloride injection often produces a decrease in blood pressure below baseline levels that is usually transient and asymptomatic but may result in dizziness. Systolic pressure less than 90 mmHg and/or diastolic pressure less than 60 mmHg was seen in 5 to 10% of patients in controlled U.S. trials in supraventricular tachycardia and in about 10% of the patients with atrial flutter/fibrillation. The incidence of symptomatic hypotension observed in studies conducted in the U.S. was approximately 1.5%. Three of the five symptomatic patients required intravenous pharmacologic treatment (levarterenol bitartrate, metaraminol bitartrate, or 10% calcium gluconate). All recovered without sequelae.

Extreme Bradycardia/Asystole

Verapamil hydrochloride injection affects the AV and SA nodes and rarely may produce second- or third-degree AV block, bradycardia, and, in extreme cases, asystole. This is more likely to occur in patients with a sick sinus syndrome (SA nodal disease), which is more common in older patients. Bradycardia associated with sick sinus syndrome was reported in 0.3% of the patients treated in controlled double-blind trials in the United States. The total incidence of bradycardia (ventricular rate less than 60 beats/min) was 1.2% in these studies. Asystole in patients other than those with sick sinus syndrome is usually of short duration (few seconds or less), with spontaneous return to AV nodal or normal sinus rhythm. If this does not occur promptly, appropriate treatment should be initiated immediately. (See ***ADVERSE REACTIONS:Treatment of Acute Cardiovascular Adverse Reactions***.)

Heart Failure

When heart failure is not severe or rate related, it should be controlled with digitalis

glycosides and diuretics, as appropriate, before verapamil hydrochloride injection is used. In patients with moderately severe to severe cardiac dysfunction (pulmonary wedge pressure above 20 mmHg, ejection fraction less than 30%), acute worsening of heart failure may be seen.

Concomitant Antiarrhythmic Therapy

Digitalis: Intravenous verapamil has been used concomitantly with digitalis preparations without the occurrence of serious adverse effects. However, since both drugs slow AV conduction, patients should be monitored for AV block or excessive bradycardia.

Procainamide: Intravenous verapamil has been administered to a small number of patients receiving oral procainamide without the occurrence of serious adverse effects.

Quinidine: Intravenous verapamil has been administered to a small number of patients receiving oral quinidine without the occurrence of serious adverse effects. However, three patients have been described in whom the combination resulted in an exaggerated hypotensive response presumably from the combined ability of both drugs to antagonize the effects of catecholamines on α-adrenergic receptors. Caution should therefore be used when employing this combination of drugs.

Beta-Adrenergic Blocking Drugs: Intravenous verapamil has been administered to patients receiving oral beta blockers without the development of serious adverse effects. However, since both drugs may depress myocardial contractility and AV conduction, the possibility of detrimental interactions should be considered. The concomitant administration of **intravenous** beta blockers and **intravenous** verapamil has resulted in serious adverse reactions (see ***CONTRAINDICATIONS***), especially in patients with severe cardiomyopathy, congestive heart failure, or recent myocardial infarction.

Disopyramide: Until data on possible interactions between verapamil and all forms of disopyramide phosphate are obtained, disopyramide should not be administered within 48 hours before or 24 hours after verapamil administration.

Flecainide: A study in healthy volunteers showed that the concomitant administration of flecainide and verapamil may have additive effects reducing myocardial contractility, prolonging AV conduction, and prolonging repolarization.

Heart Block

Verapamil hydrochloride injection prolongs AV conduction time. While high degree AV block has not been observed in controlled clinical trials in the U.S., a low percentage (less than 0.5%) has been reported in the world literature. Development of second- or third-degree AV block or unifascicular, bifascicular, or trifascicular bundle branch block requires reduction in subsequent doses or discontinuation of verapamil and institution of appropriate therapy, if needed. (See ***ADVERSE REACTIONS:Treatment of Acute Cardiovascular Adverse Reactions***.)

Hepatic and Renal Failure

Significant hepatic and renal failure should not increase the effects of a single intravenous dose of verapamil hydrochloride injection but may prolong its duration. Repeated injections of intravenous verapamil hydrochloride injection in such patients may lead to accumulation and an excessive pharmacologic effect of the drug. There is

no experience to guide use of multiple doses in such patients, and this generally should be avoided. If repeated injections are essential, blood pressure and PR interval should be closely monitored and smaller repeat doses should be utilized. Verapamil cannot be removed by hemodialysis.

Premature Ventricular Contractions

During conversion to normal sinus rhythm, or marked reduction in ventricular rate, a few benign complexes of unusual appearance (sometimes resembling premature ventricular contractions) may be seen after treatment with verapamil hydrochloride injection. Similar complexes are seen during spontaneous conversion of supraventricular tachycardias, after D.C.-cardioversion and other pharmacologic therapy. These complexes appear to have no clinical significance.

Duchenne's Muscular Dystrophy

Intravenous verapamil hydrochloride injection can precipitate respiratory muscle failure in these patients and should, therefore, be used with caution.

Increased Intracranial Pressure

Intravenous verapamil hydrochloride injection has been seen to increase intracranial pressure in patients with supratentorial tumors at the time of anesthesia induction. Caution should be taken and appropriate monitoring performed.

PRECAUTIONS

Drug Interactions

(See ***WARNINGS: Concomitant Antiarrhythmic Therapy***) Intravenous verapamil hydrochloride injection has been used concomitantly with other cardioactive drugs (especially digitalis) without evidence of serious negative drug interactions. In rare instances, including when patients with severe cardiomyopathy, congestive heart failure or recent myocardial infarction were given **intravenous** beta-adrenergic blocking agents or disopyramide concomitantly with **intravenous** verapamil, serious adverse effects have occurred. Concomitant use of verapamil hydrochloride injection with β-adrenergic blockers may result in an exaggerated hypotensive response. Such an effect was observed in one study, following the concomitant administration of verapamil and prazosin. It may be necessary to decrease the dose of verapamil and/or dose of the neuromuscular blocking agent when the drugs are used concomitantly. As verapamil is highly bound to plasma proteins, it should be administered with caution to patients receiving other highly protein bound drugs.

Other

Cimetidine: The interaction between cimetidine and chronically administered verapamil has not been studied. In acute studies of healthy volunteers, clearance of verapamil was either reduced or unchanged.

Lithium: Increased sensitivity to the effects of lithium (neurotoxicity) has been reported during concomitant verapamil-lithium therapy with either no change or an increase in serum lithium levels. The addition of verapamil, however, has also resulted in the

lowering of serum lithium levels in patients receiving chronic stable oral lithium. Patients receiving both drugs must be monitored carefully.

Carbamazepine: Verapamil therapy may increase carbamazepine concentrations during combined therapy. This may produce carbamazepine side effects such as diplopia, headache, ataxia, or dizziness.

Rifampin: Therapy with rifampin may markedly reduce oral verapamil bioavailability.

Phenobarbital: Phenobarbital therapy may increase verapamil clearance.

Cyclosporin: Verapamil therapy may increase serum levels of cyclosporin.

Inhalation Anesthetics: Animal experiments have shown that inhalation anesthetics depress cardiovascular activity by decreasing the inward movement of calcium ions. When used concomitantly, inhalation anesthetics and calcium antagonists (such as verapamil) should be titrated carefully to avoid excessive cardiovascular depression.

Neuromuscular Blocking Agents: Clinical data and animal studies suggest that verapamil may potentiate the activity of depolarizing and nondepolarizing neuromuscular blocking agents. It may be necessary to decrease the dose of verapamil and/or the dose of the neuromuscular blocking agent when the drugs are used concomitantly.

Dantrolene: Two animal studies suggest concomitant intravenous use of verapamil and dantrolene sodium may result in cardiovascular collapse. There has also been one report of hyperkalemia and myocardial depression following the coadministration of oral verapamil and intravenous dantrolene.

Pregnancy

Reproduction studies have been performed in rabbits and rats at oral verapamil doses up to 1.5 (15 mg/kg/day) and 6 (60 mg/kg/day) times the human oral daily dose, respectively, and have revealed no evidence of teratogenicity. In the rat, however, this multiple of the human dose was embryocidal and retarded fetal growth and development, probably because of adverse maternal effects reflected in reduced weight gains of the dams. This oral dose has also been shown to cause hypotension in rats. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

There have been few controlled studies to determine whether the use of verapamil during labor or delivery has immediate or delayed adverse effects on the fetus, or whether it prolongs the duration of labor or increases the need for forceps delivery or other obstetric intervention. Such adverse experiences have not been reported in the literature, despite a long history of use of verapamil hydrochloride injection in Europe in the treatment of cardiac side effects of beta-adrenergic agonist agents used to treat premature labor.

Nursing Mothers

Verapamil hydrochloride injection crosses the placental barrier and can be detected in umbilical vein blood at delivery. Also, verapamil hydrochloride injection is excreted in human milk. Because of the potential for adverse reactions in nursing infants from

verapamil, nursing should be discontinued while verapamil is administered.

Pediatrics

Controlled studies with verapamil have not been conducted in pediatric patients, but uncontrolled experience with intravenous administration in more than 250 patients, about half under 12 months of age and about 25% newborn, indicates that results of treatment are similar to those in adults. **In rare instances, however, severe hemodynamic side effects – some of them fatal – have occurred following the intravenous administration of verapamil to neonates and infants. Caution should therefore be used when administering verapamil to this group of pediatric patients.**

The most commonly used single doses in patients up to 12 months of age have ranged from 0.1 to 0.2 mg/kg of body weight, while in patients aged 1 to 15 years, the most commonly used single doses ranged from 0.1 to 0.3 mg/kg of body weight. Most of the patients received the lower dose of 0.1 mg/kg once but, in some cases, the dose was repeated once or twice every 10 to 30 minutes.

ADVERSE REACTIONS

The following reactions were reported with verapamil hydrochloride injection used in controlled U.S. clinical trials involving 324 patients:

Cardiovascular: Symptomatic hypotension (1.5%); bradycardia (1.2%); severe tachycardia (1.0%). The worldwide experience in open clinical trials in more than 7,900 patients was similar.

Central Nervous System Effects: Dizziness (1.2%); headache (1.2%). Occasional cases of seizures during verapamil injection have been reported.

Gastrointestinal: Nausea (0.9%); abdominal discomfort (0.6%).

In rare cases of hypersensitive patients, broncho/laryngeal spasm accompanied by itch and urticaria has been reported.

The following reactions have been reported at low frequency: emotional depression, rotary nystagmus, sleepiness, vertigo, muscle fatigue, diaphoresis, and respiratory failure.

Suggested Treatment of Acute Cardiovascular Adverse Reactions*

The frequency of these reactions was quite low, and experience with their treatment has been limited.

Adverse Reaction	Proven Effective Treatment	Supportive Treatment
1. Symptomatic hypotension requiring treatment	Calcium chloride (intravenous) Levarterenol bitartrate (intravenous) Metaraminol bitartrate (intravenous)	Intravenous fluids Trendelenburg

	Isoproterenol HCl (intravenous) Dopamine (intravenous)	position
1. Bradycardia, AV block, Asystole	Isoproterenol HCl (intravenous) Calcium chloride (intravenous) Cardiac pacing Levarterenol bitartrate (intravenous) Atropine (intravenous)	Intravenous fluids (slow drip)
1. Rapid ventricular rate (due to antegrade conduction in flutter/fibrillation with W-P-W or L-G-L syndromes)	DC-cardioversion (high-energy may be required) Procainamide (intravenous) Lidocaine (intravenous)	Intravenous fluids (slow drip)

*Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

OVERDOSAGE

Treatment of overdosage should be supportive and individualized. Beta-adrenergic stimulation and/or parenteral administration of calcium solutions may increase calcium ion flux across the slow channel, and have been effectively used in treatment of deliberate overdosage with oral verapamil hydrochloride. Verapamil cannot be removed by hemodialysis. Clinically significant hypotensive reactions or high degree AV block should be treated with vasopressor agents or cardiac pacing, respectively. Asystole should be handled by the usual measures including isoproterenol hydrochloride, other vasopressor agents, or cardiopulmonary resuscitation (see ***ADVERSE REACTIONS: Suggested Treatment of Acute Cardiovascular Adverse Reactions***).

DOSAGE AND ADMINISTRATION (For intravenous Use Only)

VERAPAMIL HYDROCHLORIDE INJECTION SHOULD BE GIVEN AS A SLOW INTRAVENOUS INJECTION OVER AT LEAST A TWO MINUTE PERIOD OF TIME UNDER CONTINUOUS ELECTROCARDIOGRAPHIC AND BLOOD PRESSURE MONITORING.

The recommended intravenous doses of verapamil hydrochloride injection are as follows:

ADULT: Initial dose – 5 to 10 mg (0.075 to 0.15 mg/kg body weight) given as an intravenous bolus over at least 2 minutes.

Repeat dose – 10 mg (0.15 mg/kg body weight) 30 minutes after the first dose if the initial response is not adequate. An optimal interval for subsequent intravenous doses

has not been determined, and should be individualized for each patient.

Older patients – The dose should be administered over at least 3 minutes to minimize the risk of untoward drug effects.

PEDIATRIC: Initial dose:

0 to 1 yr: 0.1 to 0.2 mg/kg body weight (usual single dose range: 0.75 to 2 mg) should be administered as an intravenous bolus over at least 2 minutes **under continuous ECG monitoring.**

1 to 15 yrs: 0.1 to 0.3 mg/kg body weight (usual single dose range: 2 to 5 mg) should be administered as an intravenous bolus over at least 2 minutes. **Do not exceed 5 mg.**

Repeat dose:

0 to 1 yr: 0.1 to 0.2 mg/kg body weight (usual single dose range: 0.75 to 2 mg) 30 minutes after the first dose if the initial response is not adequate **(under continuous ECG monitoring)**. An optimal interval for subsequent intravenous doses has not been determined, and should be individualized for each patient.

1 to 15 yrs: 0.1 to 0.3 mg/kg body weight (usual single dose range: 2 to 5 mg) 30 minutes after the first dose if the initial response is not adequate. **Do not exceed 10 mg as a single dose**. An optimal interval for subsequent intravenous doses has not been determined, and should be individualized for each patient.

Note: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Verapamil hydrochloride injection is physically compatible and chemically stable for at least 24 hours at 25°C protected from light in most common large volume parenteral solutions. Admixing verapamil hydrochloride injection with albumin, amphotericin B, hydralazine HCl and trimethoprim with sulfamethoxazole should be avoided. Verapamil hydrochloride injection will precipitate in any solution with a pH above 6.0.

HOW SUPPLIED

Verapamil Hydrochloride Injection USP, 5 mg/2 mL and 10 mg/4 mL (2.5 mg/mL), is supplied in single-dose vials as follows:

NDC 59923-605-02 One carton containing 5 x 2 mL Single-Dose Vials

NDC 59923-606-04 One carton containing 5 x 4 mL Single-Dose Vials

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Protect from light by retaining in package until ready to use.

Manufactured for:

Areva Pharmaceuticals Inc.

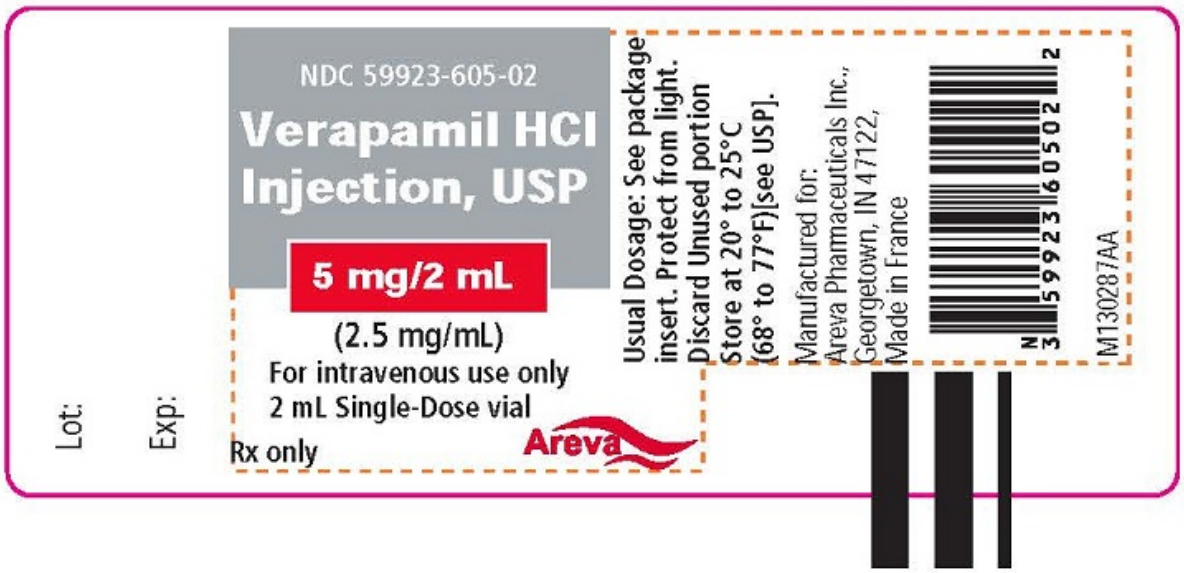
Georgetown, IN 47122

Made in France

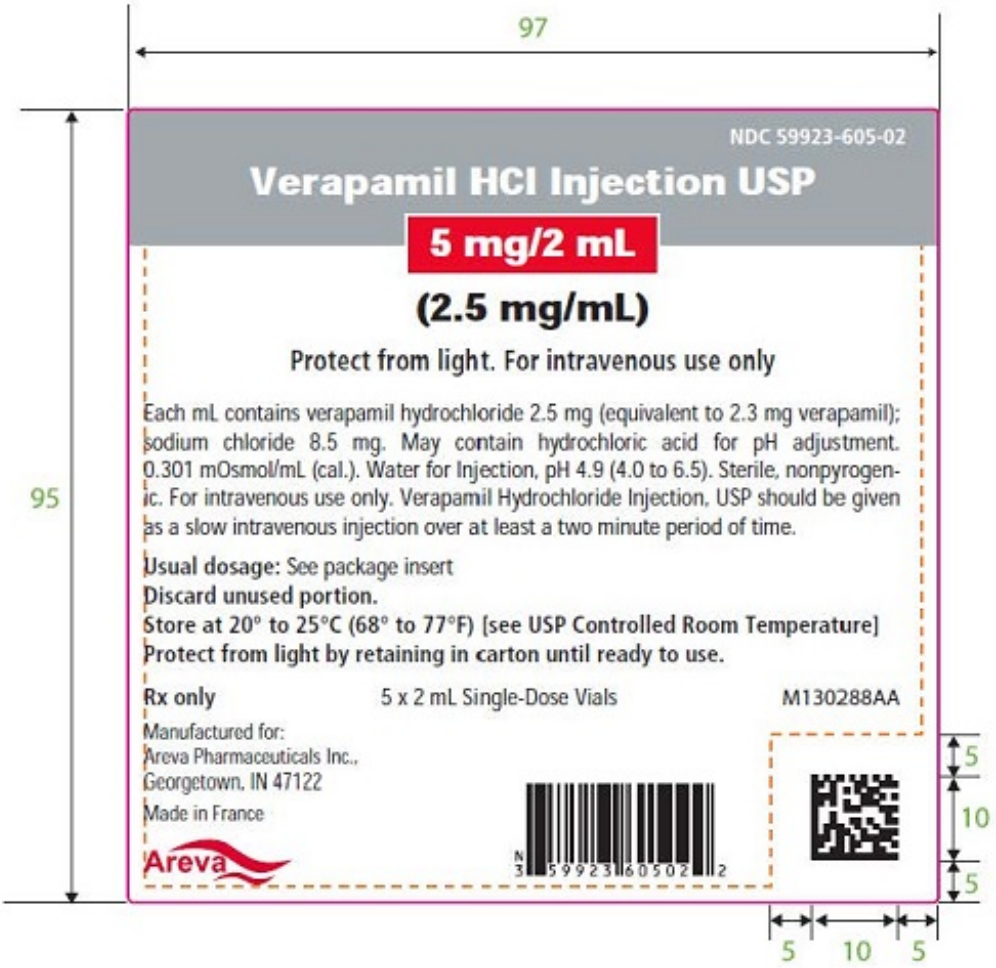
Revised: February 2019

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

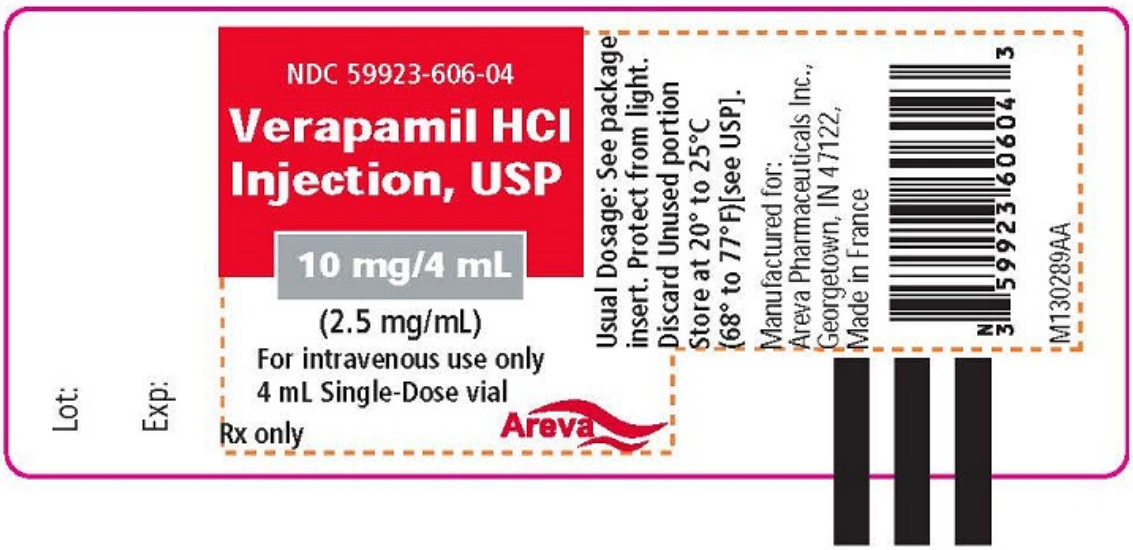
2 mL Container Vial Label



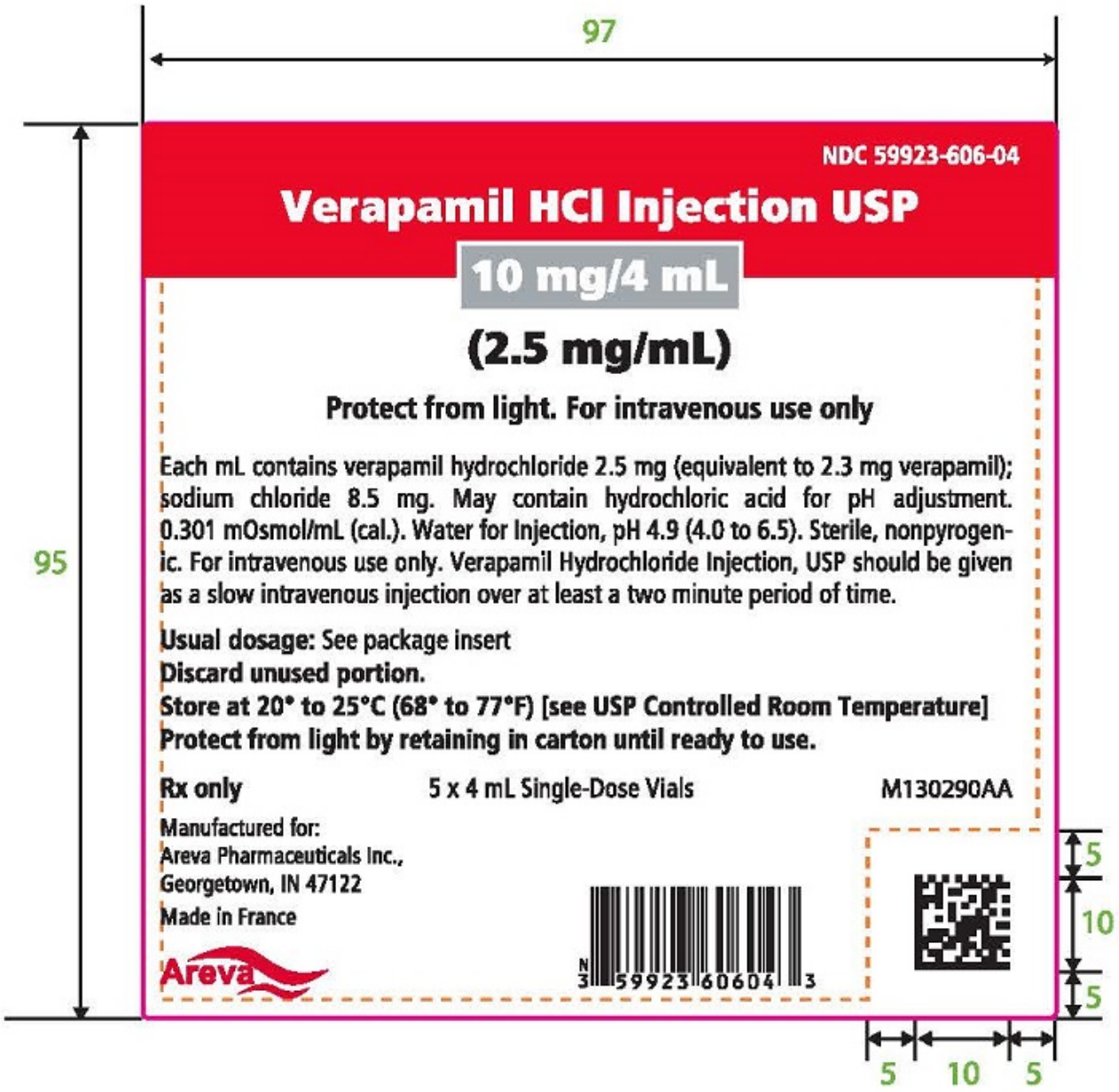
2 mL Carton Label



4 mL Container Vial Label



4 mL Carton Label



VERAPAMIL HYDROCHLORIDE

verapamil hydrochloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59923-605
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
VERAPAMIL HYDROCHLORIDE (UNII: V3888OEY5R) (VERAPAMIL - UNII:CJ0O37KU29)	VERAPAMIL HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59923-605-02	5 in 1 CARTON	01/01/2025	
1		2 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213352	01/01/2020	

VERAPAMIL HYDROCHLORIDE

verapamil hydrochloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59923-606
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
VERAPAMIL HYDROCHLORIDE (UNII: V3888OEY5R) (VERAPAMIL - UNII:CJ0O37KU29)	VERAPAMIL HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59923-606-	5 in 1 CARTON	01/01/2025	

1	04	5 in 1 CARTON	01/01/2025	
1		4 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213352	01/01/2025	

Labeler - Areva Pharmaceuticals (833189835)

Establishment

Name	Address	ID/FEI	Business Operations
Recipharm Monts		777990813	manufacture(59923-606, 59923-605)

Revised: 5/2021 Areva Pharmaceuticals