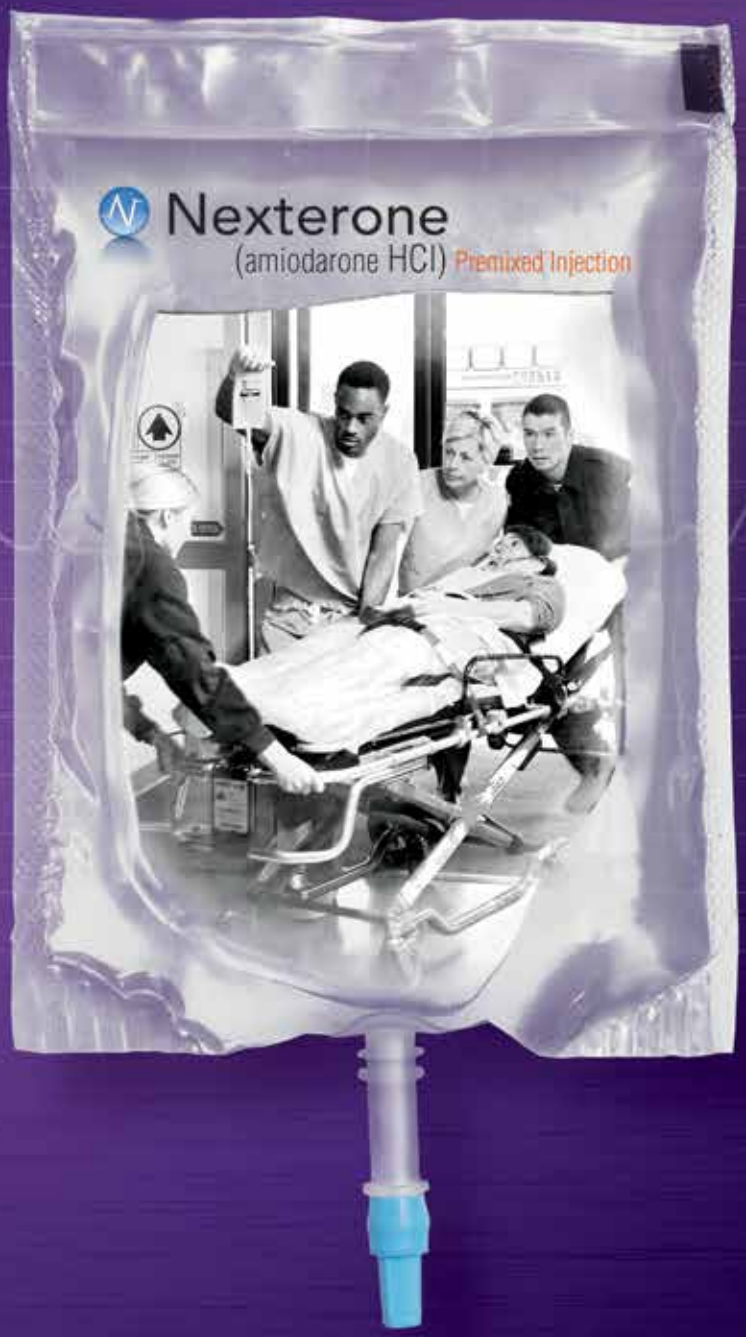
AT A MOMENT'S NOTICE

Manufacturer-prepared NEXTERONE (amiodarone HCl)
Ready for you. Ready for the patient.



Indications and Usage

NEXTERONE (amiodarone HCl) Premixed Injection is indicated for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation (VF) and hemodynamically unstable ventricular tachycardia (VT) in patients refractory to other therapy. NEXTERONE also can be used to treat patients with VT/VF for whom oral amiodarone is indicated, but who are unable to take oral medication. During or after treatment with NEXTERONE, patients may be transferred to oral amiodarone therapy.

Use NEXTERONE for acute treatment until the patient's ventricular arrhythmias are stabilized. Most patients will require this therapy for 48 to 96 hours, but NEXTERONE may be safely administered for longer periods if necessary.

Please see Indications and Important Risk Information on pages 10-11 and full Prescribing Information inside pocket.

Baxter

Emergency Department Nurse

Because emergencies are unpredictable.

Long-Term Acute Care Clinician

Because the moment I call for amiodarone, a pharmacy might not be an option.

Cardiologist

Because fast and accurate preparation makes a difference.

NEXTERONE (amiodarone HCl) is ready for clinicians to deliver an immediate and accurately prepared dose.

Emergency Medical Service Paramedic

Because every second is crucial.

Cath Lab Cardiac Physiologist

Because ready-to-use can help control the potential for compounding errors.

Minimize errors related to compounding by using manufacturer-prepared NEXTERONE

NEXTERONE provides a ready-to-use amiodarone in 150 mg/100 mL and 360 mg/200 mL administration bags. A premix that is cGMP manufacturer prepared provides an accurately prepared dose to help minimize compounding errors that may occur in urgent situations. With NEXTERONE, there's no waiting, no admixing–and it may reduce amiodarone waste. Clinicians can just grab the bag for delivery to the patient.

Selected Important Risk Information: NEXTERONE should be administered only by physicians who are experienced in the treatment of life-threatening arrhythmias, who are thoroughly familiar with the risks and benefits of amiodarone therapy, and who have access to facilities adequate for monitoring the effectiveness and side effects of treatment.

Intensive Care Unit Director

Because in patient situations, accuracy and time are very important.

Nexterone (amiodarone HCl) Premixed Injection

Please see Indications and Important Risk Information on pages 10-11 and full Prescribing Information inside pocket.

Emergency Department Nurse

I need NEXTERONE premix because emergencies are unpredictable.

In the emergency department, it's impossible to predict what sort of situation will come through the doors. That's why preparation is key, and why healthcare professionals embrace potential error-reducing solutions.

NEXTERONE (amiodarone HCl) Premixed Injection is ready to use, equipping clinicians for the unexpected. So when the emergency department doors open and a patient needs amiodarone, NEXTERONE offers immediate medication administration.

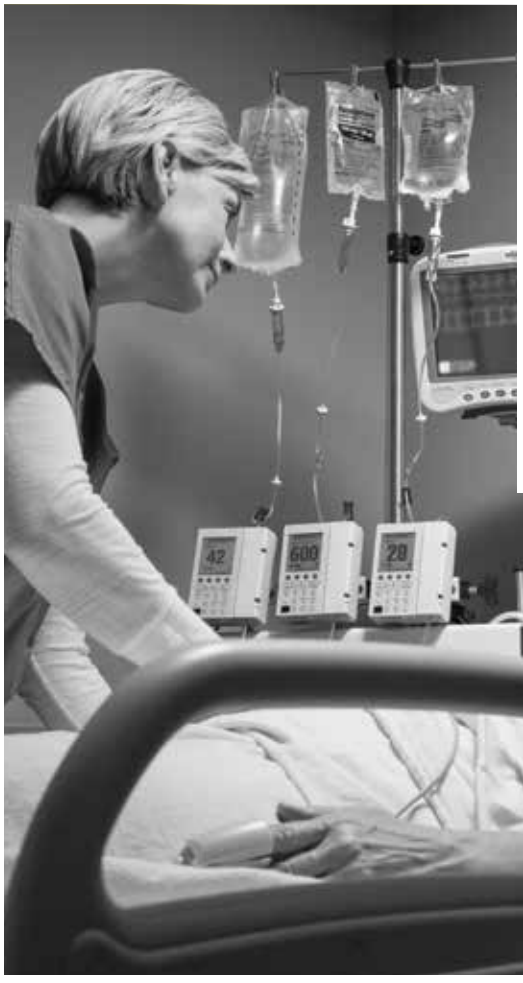
- NEXTERONE means your dose is ready and accurately prepared
- With no mixing necessary, NEXTERONE offers immediate medication administration
- In critical situations where mistakes are amplified, ready-to-use NEXTERONE can be key

Selected Important Risk Information: NEXTERONE (amiodarone HCl) Premixed Injection is contraindicated in patients with known hypersensitivity to any of the components of NEXTERONE, including iodine, cardiogenic shock, marked sinus bradycardia, and second- or third-degree atrio-ventricular (AV) block unless a functioning pacemaker is available.

Nexterone
(amiodarone HCl) Premixed Injection

Intensive Care Unit Director

I need NEXTERONE premix because in patient situations, accuracy and time are very important.



When a patient situation is critical, the clinician needs to provide an exact concentration. NEXTERONE (amiodarone HCl) delivers manufacturer-prepared amiodarone, a premixed injection formulation that is free of human contact during the filling process.

For intensive care settings, NEXTERONE is an accurately prepared option. NEXTERONE has a shelf life of 2 years,* which allows for extended storage on crash carts.

- Manufacturing of NEXTERONE includes exclusive aseptic bag filling technology
- Eliminates the need and stress of admixing with ready-to-administer bags
- Premixed NEXTERONE offers healthcare professionals an accurately prepared dose

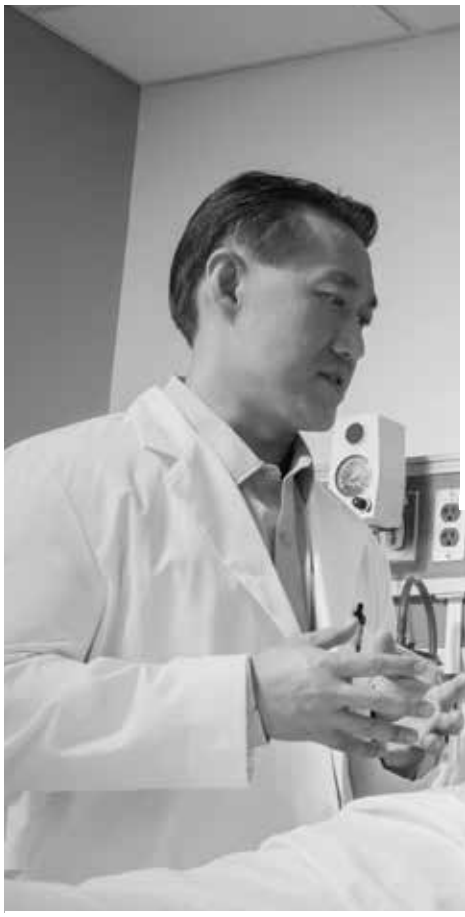
*Store in carton to protect from light until ready to use.

Please see Indications and Important Risk Information on pages 10-11 and full Prescribing Information inside pocket.

Nexterone
(amiodarone HCl) Premixed Injection

Cardiologist

I need NEXTERONE premix because fast and accurate preparation makes a difference.

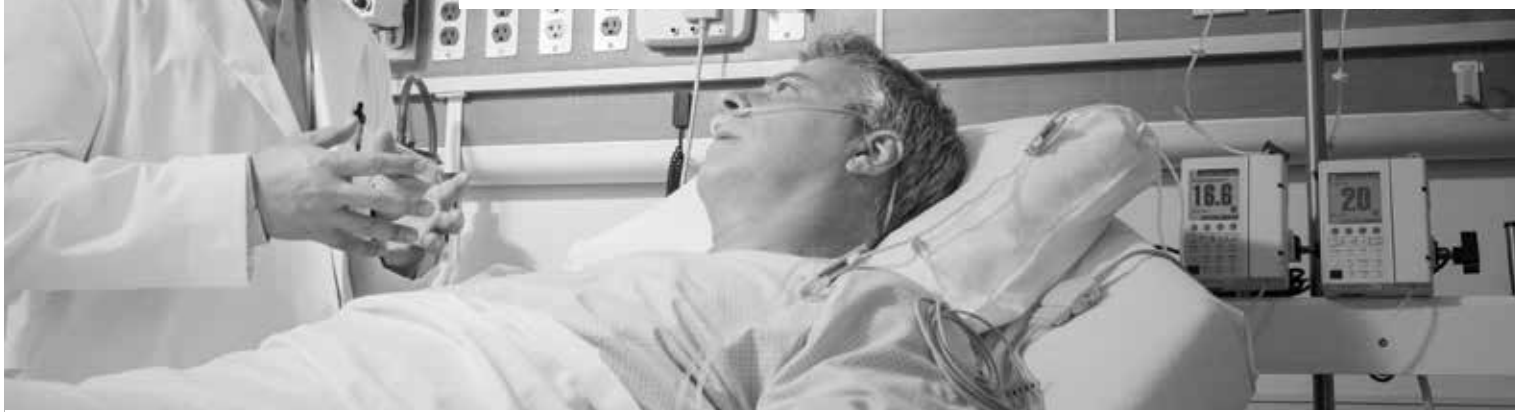


Cardiologists anticipate the possibility of needing amiodarone. NEXTERONE (amiodarone HCl) has a 2-year shelf life* and can be stored at the point of care for emergencies.

NEXTERONE allows for immediate amiodarone administration without having to wait for your prescription to be compounded, labeled, and delivered.

- NEXTERONE premixed amiodarone has a shelf life of 2 years*
- Accurate concentration for timely administration from a premixed bag
- NEXTERONE is available for immediate use when indicated

*Store in carton to protect from light until ready to use.



Selected Important Risk Information: NEXTERONE may cause worsening of existing arrhythmias or precipitate a new arrhythmia sometimes leading to fatal outcomes. Monitor patients for QTc prolongation during infusion with NEXTERONE. Reserve the combination of amiodarone with other antiarrhythmic therapies that prolong the QTc to patients with life-threatening ventricular arrhythmias who are incompletely responsive to a single agent. Amiodarone causes thyroid dysfunction in some patients, which may lead to potentially fatal breakthrough or exacerbated arrhythmia.

Cath Lab Cardiac Physiologist

I need NEXTERONE premix because ready-to-use can help control the potential for compounding errors.

When an emergency occurs in the cath lab, make sure that your healthcare professionals have one less task to perform. NEXTERONE (amiodarone HCl), the premixed injection, is available for immediate administration without having to send an order to the in-house pharmacy or admix it in the department.

In stressful situations, NEXTERONE provides clinicians with ready-to-use amiodarone when it is indicated. NEXTERONE has a 2-year shelf life* at room temperature and can sit on the cart, ready for administration when needed.

- NEXTERONE is ready to administer, in both loading and maintenance doses
- A 2-year shelf life*—premixed amiodarone is available when you need it
- NEXTERONE offers healthcare professionals one less task to perform during stressful situations

*Store in carton to protect from light until ready to use.

Please see Indications and Important Risk Information on pages 10-11 and full Prescribing Information inside pocket.

Nexterone
(amiodarone HCl) Premixed Injection

Long-Term Acute Care Clinician

I need NEXTERONE premix because the moment I call for amiodarone, a pharmacy may not be an option.

In long-term acute care, being prepared for critical situations is all-important. That includes making patient maintenance adjustable with the touch of a button. NEXTERONE (amiodarone HCl) uses bar-coded bags, so clinicians and pharmacists can track NEXTERONE usage within the institution.

Manufacturer-prepared NEXTERONE premixed amiodarone has a 2-year shelf life.* Our proprietary containers and cGMP aseptic-fill technology allow for a 24-month—not hour—shelf life.*

- NEXTERONE premixed bags provide accurate concentration at the point of care
- NEXTERONE is ready to use
- NEXTERONE premixed amiodarone has a shelf life of 2 years,* which allows for extended storage at room temperature

*Store in carton to protect from light until ready to use.

Paramedic

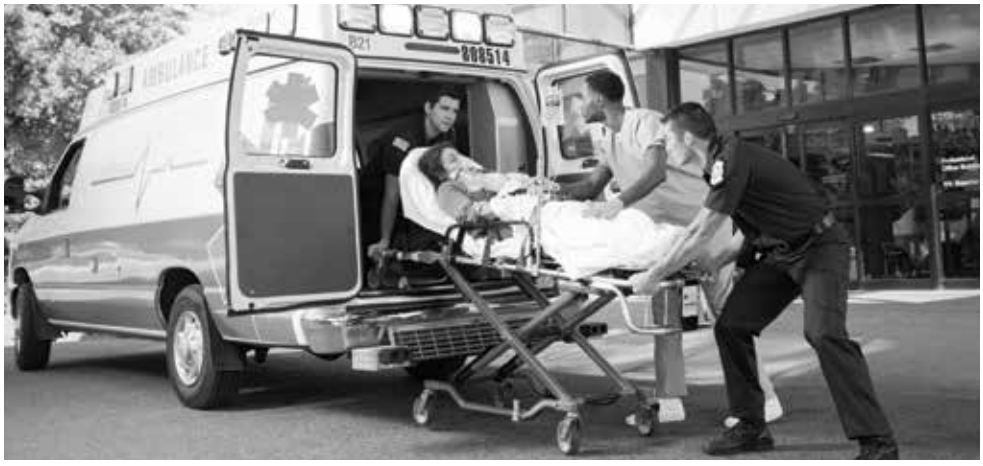
I need NEXTERONE premix because every second is crucial.

As the initial point of care in many critical situations, EMS paramedics have to ensure that the right dose is prepared the first time. Ready-to-use NEXTERONE is made with urgency in mind. In critical situations, admixing may lead to delays and potential for errors. NEXTERONE aims to help minimize error-causing compounding delays with the only manufacturer-prepared premixed amiodarone available.

NEXTERONE has a 24-month shelf life* when stored at room temperature, allowing for amiodarone administration when needed.

- In stressful, time-sensitive situations, premixed amiodarone is ready for your patients
- At room temperature, NEXTERONE has a 2-year shelf life*

*Store in carton to protect from light until ready to use.



Selected Important Risk Information: NEXTERONE should be administered only by physicians who are experienced in the treatment of life-threatening arrhythmias, who are thoroughly familiar with the risks and benefits of amiodarone therapy, and who have access to facilities adequate for monitoring the effectiveness and side effects of treatment.

Please see Indications and Important Risk Information on pages 10-11 and full Prescribing Information inside pocket.

DOSING CHART FIRST 24 HOURS

Nexterone (amiodarone HCl) Premixed Injection	150 mg/100 mL (Bag Size) 	360 mg/200 mL (Bag Size) 	
DOSE	150 mg	360 mg	540 mg
CONCENTRATION	1.5 mg/mL	1.8 mg/mL	1.8 mg/mL
INFUSION TIME **INFUSION RATE**	10 minutes 15 mg/min	6 hours 1 mg/min	Remaining 18 hours 0.5 mg/min
INFUSION PUMP RATE  *	10 mL/min 600 mL/hr	0.556 mL/min 33.36 mL/hr	0.278 mL/min 16.68 mL/hr

Rx only. For the safe and proper use of this device, refer to the complete instructions in the Operator's Manual.

* Pump displayed is for example only.

- The first 24-hour dose may be individualized for each patient; however, in controlled clinical trials, mean daily dose above 2100 mg was associated with an increased risk of hypotension. Do not exceed an initial infusion rate of 30 mg/min
- After the first 24 hours, continue the maintenance infusion rate of 0.5 mg/min. The rate of the maintenance infusion may be increased to achieve effective arrhythmia suppression
- In the event of breakthrough episodes of VF or hemodynamically unstable VT, use 150 mg supplemental infusions of NEXTERONE (amiodarone HCl) Premixed Injection (infused over 10 minutes to minimize the potential for hypotension)
- Single-use only. Administer via central venous catheter whenever possible. Use an in-line filter

Indications and Important Risk Information

Indications and Usage

NEXTERONE (amiodarone HCl) Premixed Injection is indicated for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation (VF) and hemodynamically unstable ventricular tachycardia (VT) in patients refractory to other therapy. NEXTERONE also can be used to treat patients with VT/VF for whom oral amiodarone is indicated, but who are unable to take oral medication. During or after treatment with NEXTERONE, patients may be transferred to oral amiodarone therapy.

Use NEXTERONE for acute treatment until the patient's ventricular arrhythmias are stabilized. Most patients will require this therapy for 48 to 96 hours, but NEXTERONE may be safely administered for longer periods if necessary.

Important Risk Information

NEXTERONE (amiodarone HCl) Premixed Injection is contraindicated in patients with:

- Known hypersensitivity to any of the components of NEXTERONE, including iodine
- Cardiogenic shock
- Marked sinus bradycardia
- Second- or third-degree atrio-ventricular (AV) block unless a functioning pacemaker is available

- NEXTERONE should be administered only by physicians who are experienced in the treatment of life-threatening arrhythmias, who are thoroughly familiar with the risks and benefits of amiodarone therapy, and who have access to facilities adequate for monitoring the effectiveness and side effects of treatment.
- Because of the long half-life of amiodarone and its metabolite desethylamiodarone, the potential for adverse reactions or interactions, as well as observed adverse effects, can persist following amiodarone withdrawal.
- Hypotension is the most common adverse reaction seen with intravenous amiodarone. Clinically significant hypotension during infusions was seen most often in the first several hours of treatment and appeared to be related to the rate of infusion. Monitor the initial rate of infusion closely and do not

exceed the recommended rate. In some cases, hypotension may be refractory and result in a fatal outcome. Treat hypotension initially by slowing the infusion; additional standard therapy may be needed, including: vasopressors, positive inotropic agents and volume expansion.

- Drug-related bradycardia that was not dose-related occurred while patients were receiving intravenous amiodarone for life-threatening VT/VF. Treat bradycardia by slowing the infusion rate or discontinuing NEXTERONE. Treat patients with a known predisposition to bradycardia or AV block with NEXTERONE in a setting where a temporary pacemaker is available.
- Elevations of blood hepatic enzyme values ALT, AST, GGT are commonly seen in patients with immediately life-threatening VT/VF. Elevated bilirubin levels have been reported in patients administered intravenous amiodarone. In patients with life-threatening arrhythmias, the potential risk of hepatic injury should be weighed against the potential benefit of NEXTERONE therapy. Carefully monitor patients receiving NEXTERONE for evidence of progressive hepatic injury. In such cases, consider reducing the rate of administration or withdrawing NEXTERONE.
- NEXTERONE may cause worsening of existing arrhythmias or precipitate a new arrhythmia sometimes leading to fatal outcomes. Monitor patients for QTc prolongation during infusion with NEXTERONE. Reserve the combination of amiodarone with other antiarrhythmic therapies that prolong the QTc to patients with life-threatening ventricular arrhythmias who are incompletely responsive to a single agent. Amiodarone causes thyroid dysfunction in some patients, which may lead to potentially fatal breakthrough or exacerbated arrhythmia.
- Two percent (2%) of patients were reported to have acute respiratory distress syndrome (ARDS) during clinical studies involving 48 hours of therapy. There have been reports of early development of pulmonary fibrosis (within 1 to 3 months) following initiation of amiodarone treatment. Pulmonary toxicity including pulmonary fibrosis is a well-recognized complication of long-term amiodarone use.
- Cases of optic neuropathy and optic neuritis, usually resulting in visual impairment, have been reported in patients treated with oral or intravenous amiodarone. In some cases, visual impairment has progressed to permanent blindness. Optic neuropathy and neuritis may occur at any time following initiation of therapy. A causal relationship to the drug has not been clearly established. Perform an ophthalmic examination if symptoms of visual impairment appear, such as changes in visual acuity and decreases in peripheral vision. Re-evaluate the necessity of amiodarone therapy if optic neuropathy or neuritis is suspected. Perform regular ophthalmic examination, including fundoscopy and slit-lamp examination, during administration of NEXTERONE.
- Amiodarone inhibits peripheral conversion of thyroxine (T4) to triiodothyronine (T3) and may cause increased T4 levels, decreased T3 levels, and increased levels of inactive reverse T3 (rT3) in clinically euthyroid patients. Amiodarone can cause either hypothyroidism or hyperthyroidism. Evaluate thyroid function prior to treatment and periodically thereafter, particularly in elderly patients, and in any patient with a history of thyroid nodules, goiter, or other thyroid dysfunction. Because of the slow elimination of amiodarone and its metabolites, high plasma iodide levels, altered thyroid function, and abnormal thyroid function tests may persist for several weeks or even months following NEXTERONE withdrawal. Amiodarone causes hyperthyroidism in about 2% of patients. Thyrotoxicosis and arrhythmia with fatal outcome has been reported in the presence of pre-existing hyperthyroidism even following a single intravenous amiodarone dose. Consider the possibility of hyperthyroidism if any new signs of arrhythmia appear. Hypothyroidism has been reported in 2-10% of patients receiving amiodarone. Cases of severe hypothyroidism and myxedema coma, sometimes fatal, have been reported in association with amiodarone therapy. Manage hypothyroidism by reducing the dose of or discontinuing NEXTERONE and considering the need for thyroid hormone supplement.
- Inform the patient that amiodarone can cause fetal harm if NEXTERONE is administered during pregnancy or if the patient becomes pregnant while taking NEXTERONE.
- Anaphylactic/anaphylactoid reactions have been reported with intravenous amiodarone including shock (sometimes fatal), cardiac arrest, and the following manifestations: hypotension, tachycardia, hypoxia, cyanosis, rash, flushing, hyperhidrosis and cold sweat. Since NEXTERONE contains dextrose, patients with allergy to corn or corn products are at risk for allergic reaction.
- The most important adverse reactions were hypotension, asystole/cardiac arrest/pulseless electrical activity (PEA), cardiogenic shock, congestive heart failure, bradycardia, liver function test abnormalities, VT, and AV block. The most common adverse reactions leading to discontinuation of intravenous amiodarone therapy were hypotension (1.6%), asystole/cardiac arrest/PEA (1.2%), VT (1.1%), and cardiogenic shock (1%).
- Amiodarone is metabolized to the active metabolite desethylamiodarone (DEA) by the cytochrome P450 (CYP450) enzyme group, specifically CYP3A and CYP2C8. Amiodarone has the potential for interactions with drugs or substances that may be substrates, inhibitors or inducers of CYP450 enzymes. Amiodarone and DEA inhibits p-glycoprotein and certain CYP450 enzymes CYP1A2, CYP2C9, CYP2D6, and CYP3A, increasing exposure to other drugs. The metabolism of quinidine, procainamide, flecainide can be inhibited by amiodarone. In patients receiving digoxin therapy, administration of oral amiodarone results in an increase in serum digoxin concentration. Reduce dose of digoxin by half or discontinue digoxin. If digitalis treatment is continued, monitor serum levels. Limit the dose of simvastatin in patients on amiodarone to 20 mg daily. Limit the daily dose of lovastatin to 40 mg. Lower starting and maintenance doses of other CYP3A4 substrates (e.g., atorvastatin) may be required as amiodarone may increase the plasma concentration of these drugs. Potentiation of warfarin-type (CYP2C9 and CYP3A substrate) anticoagulant response is almost always seen in patients receiving amiodarone and can result in serious or fatal bleeding, therefore reduce the dose of the anticoagulant by one-third to one-half, and monitor INR closely. Monitor cyclosporine drug levels and renal function in patients taking both drugs. Increased steady-state levels of phenytoin during concomitant therapy with amiodarone have been reported. Monitor phenytoin levels in patients taking both drugs.

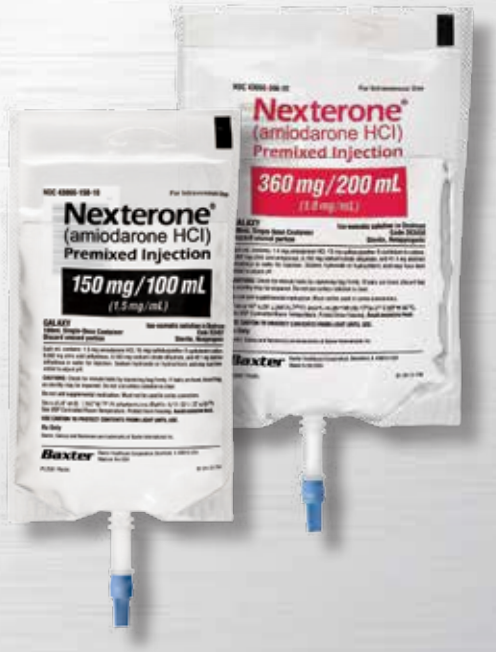
NEXTERONE (amiodarone HCl) is there for clinicians who need to deliver an immediate and accurately prepared dose

Nexterone
(amiodarone HCl) Premixed Injection

NEXTERONE Premixed Injection from Baxter

Amiodarone is available as a cGMP manufacturer-prepared, ready-to-use premixed intravenous injection.

Having NEXTERONE ready at the point of care reduces the risk of contamination related to compounding and delay when clinicians need to focus on patient care. No waiting, no admixing, and may reduce amiodarone waste on the department floor. Clinicians can just grab the bag for delivery to the patient.



- Available in 150 mg/100 mL and 360 mg/200 mL containers
- 2-year shelf life* at room temperature
- No admixing
- Can be stored in automated dispensing cabinets/crash carts
- Exclusive aseptic bag-filling technology
- Bar coded for bedside scanning
- Non-PVC and non-DEHP GALAXY containers
- Free of polysorbate 80 and benzyl alcohol cosolvents

To order NEXTERONE, contact your Baxter pharmacy representative or call 888-229-0001.

Description	Product Code	Strength/ Volume	Concentration	NDC #	Pack Factor (cartons/case)
NEXTERONE (amiodarone HCl) Premixed Injection	2G3451	150 mg/100 mL	1.5 mg/mL	43066-150-10	12
	2G3450	360 mg/200 mL	1.8 mg/mL	43066-360-20	10

*Store in carton to protect from light until ready to use.

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nexterone.com

Baxter Healthcare Corporation
Route 120 and Wilson Road
Round Lake, IL 60073

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Baxter