

Amiodarone HCl Hameln 50 mg/ml, concentrate for solution for injection/infusion

What is Amiodarone HCl Hameln 50 mg/ml and what is it used for?

Amiodarone is used for the treatment of irregular heart rhythm, called "arrhythmias." Amiodarone works by controlling your heart when it beats abnormally.

Amiodarone HCl Hameln 50 mg/ml is given when a rapid response is necessary or when you are unable to take tablets. Your doctor will administer this medication to you, and you will remain under observation in a hospital or by a specialist.

When should you not use this medicine or use it with extra caution?

When should you not use this medicine?

- If you are allergic to amiodarone, iodine, or any of the ingredients in this medicine.
- If you have a slower heart rate than usual (called sinus bradycardia) or if you suffer from a condition that causes an irregular heart rate (such as sinoatrial block, sick sinus syndrome, where the heart sometimes beats too fast or too slow).
- If you have other heart problems and do not have a pacemaker. For example, if you have a specific disorder in the conduction of electrical impulses in the heart, leading to cardiac arrhythmias (AV block).
- If your thyroid is not functioning properly. Your doctor needs to test your thyroid before prescribing this medicine.
- If you are taking other medications that can affect your heart rate (see also "Are you taking any other medications?").
- If the person receiving this medicine is a premature baby or a newborn baby (not premature).
- If you are on the waiting list for a heart transplant, your doctor may adjust your treatment. The use of amiodarone before a heart transplant can increase the risk of a life-threatening condition called primary graft dysfunction, in which the transplanted heart does not function properly within the first 24 hours after the surgery.

When should this medicine not be administered?

- If you are pregnant or breastfeeding (its use is only allowed in life-threatening situations).

When should you use this medicine with extra caution?

Your doctor will carefully and regularly monitor your electrocardiogram (ECG), blood pressure, liver function, and thyroid function:

- If you have a weak heart or insufficient pumping capacity of the heart (heart failure).
- If you have low blood pressure.
- If you have liver problems.
- If you have lung problems, including sudden onset of breathlessness due to bronchospasm and swelling of the respiratory mucosa (asthma).
- If you have thyroid problems.

Be extra cautious with amiodarone hydrochloride 50 mg/ml. Contact your doctor, pharmacist, or nurse if:

- You experience vision problems. This can also be a condition called "optic neuropathy" or "neuritis" (eye pain and impaired vision).
- The person receiving this medication is a child or a toddler under 3 years of age.
- You develop blisters on the skin or skin bleeding, including around your lips, eyes, mouth, nose, vagina, or penis. You may also have flu-like symptoms and fever. This can be a condition called "Stevens-Johnson syndrome."
- You develop a severe skin rash. You may experience fever, blisters, peeling of the skin, and detachment of the skin. You may also feel unwell, have fever, chills, and muscle pain (Toxic Epidermal Necrolysis).
- You are currently taking the medication sofosbuvir for the treatment of hepatitis C because it can cause a life-threatening slowing of your heart rate. Your doctor may consider alternative treatments. If treatment with amiodarone and sofosbuvir is necessary, additional heart monitoring may be required.

Immediately inform your doctor if you are currently using medications containing sofosbuvir for the treatment of hepatitis C and experience:

- Slow or irregular heartbeat or cardiac arrhythmias.
- Shortness of breath or worsening of existing shortness of breath.
- Chest pain.
- Light-headedness.
- Palpitations.
- Near-fainting or fainting.

Contact your doctor if any of the above-mentioned warnings apply to you or have applied to you in the past.

Are you taking any other medications?

If you are taking or have recently taken any other medications, or if there is a possibility that you will use other medications in the near future, inform your doctor or pharmacist. This is particularly important for the following medications as they can affect the effectiveness of amiodarone:

- Medications for the treatment of irregular heart rhythm (such as quinidine, procainamide, disopyramide, and sotalol).
- Medications to improve blood flow to the brain (such as vincamine).
- Medications for the treatment of mental disorders (psychiatric conditions) (such as sultopride, sulpiride, pimozide) and certain types of medications called phenothiazines (such as thioridazine).

Medications used for digestive problems (such as cisapride);

- Medications for the treatment of infections (such as moxifloxacin, erythromycin);
- Injections of pentamidine (used for certain types of pneumonia);
- Certain medications used for depression (antidepressants) (such as amitriptyline, clomipramine, dosulepin, doxepin, imipramine, lofepramine, nortriptyline, trimipramine, maprotiline);
- Medications used for hay fever, rash, or other allergies called antihistamines (such as terfenadine);
- Medications for the treatment of malaria (such as halofantrine).

Not recommended

It is not recommended to use the following medications simultaneously with Amiodarone HCl hameln 50 mg/ml:

- Medications for the treatment of heart problems and high blood pressure called beta-blockers (such as propranolol);
- Medications for the treatment of chest pain (angina) or high blood pressure called calcium channel blockers (such as diltiazem or verapamil).

Caution

Exercise caution when using the following medications in combination with amiodarone. These medications can cause low levels of potassium in the blood, which can increase the risk of life-threatening irregular heartbeat.

- Laxatives - used for constipation (such as bisacodyl, senna).
- Adrenal cortex hormones (corticosteroids) - used for inflammation (such as prednisolone).
- Tetracosactide - used to test certain hormonal disorders.
- Diuretics - used to improve urination (such as furosemide).
- Amphotericin, when administered directly into a vein - used for fungal infections.
- Amiodarone HCl hameln 50 mg/ml can enhance the effects of the following medications:
- Anticoagulant medications (such as warfarin) - your doctor needs to adjust your dose and closely monitor your treatment.
- Phenytoin - used to treat uncontrollable body seizures, often as part of an epileptic seizure.
- Digoxin - used for heart problems. Your doctor needs to closely monitor your treatment and may adjust your digoxin dose.
- Flecainide - used for irregular heartbeat. Your doctor needs to closely monitor your treatment and may adjust your flecainide dose.
- Medications for the treatment of high cholesterol called statins (such as simvastatin or atorvastatin).
- Cyclosporine, tacrolimus, and sirolimus - used to prevent organ rejection after transplantation.
- Fentanyl - used for pain relief.
- Lidocaine - a local anesthetic.
- Sildenafil - used to treat erectile dysfunction.
- Midazolam and triazolam - used to help you relax, for example, before a medical procedure.
- Ergotamine - used for migraine.

Surgery: If you need to undergo surgery, you must inform the doctors treating you that you are using this medication.

What should you pay attention to regarding food and drinks?

Do not drink grapefruit juice while using this medication. This is because drinking grapefruit juice during the use of amiodarone can increase your risk of side effects.

Pregnancy and breastfeeding

Your doctor will only prescribe this medication if they believe that the benefits of the treatment outweigh the risks during your pregnancy. This medication should only be used during pregnancy in life-threatening situations.

This medication should not be administered if you are breastfeeding. If you are receiving amiodarone during pregnancy or breastfeeding, you must discontinue breastfeeding.

Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Then contact your doctor or pharmacist before using this medication.

Driving and using machinery

Amiodarone may affect your ability to drive or use machinery. Do not drive a car or use machinery if you experience these effects. In that case, consult your doctor for advice.

Amiodarone HCl hameln 50 mg/ml contains benzyl alcohol

This medication contains 22.2 mg of benzyl alcohol per ml. Benzyl alcohol can cause toxic allergic reactions. Benzyl alcohol has been associated with the risk of serious side effects, including respiratory problems (known as "gaspings" syndrome) in young children. Do not administer to your newborn baby (less than 4 weeks old) unless recommended by your doctor. Do not use for more than one week in young children (less than 3 years old) unless advised by your doctor or pharmacist.

Consult your doctor or pharmacist for advice if you have a liver or kidney disease if you are pregnant or breastfeeding (see section 2 - Pregnancy and breastfeeding). Large amounts of benzyl alcohol can accumulate in your body and cause side effects (called metabolic acidosis).

How to use this medication?

Amiodarone is administered by a doctor or nurse into a vein (intravenous injection or infusion).

Dosage

The daily dose of this medication depends on the severity of your condition. Your doctor will determine the dosage and treatment times and adjust them specifically for you.

The recommended dosage is 5 mg per kg body weight, unless otherwise prescribed by your doctor. Your medication will be injected over a minimum period of 3 minutes.

When this medication is administered as an intravenous injection:

- You should not receive a dose higher than 5 mg per kg body weight.
- The dose must be administered slowly over a minimum period of 3 minutes (except when the medication is given for resuscitation).
- The doctor must wait at least 15 minutes before giving you another injection.
- Repeated or continuous administration can cause inflammation of the vein and damage to the skin at the injection site (the surrounding skin may feel warm and tender and appear red), and in this situation, a "central venous catheter" is recommended for use by your doctor.
- When this medication is administered as an intravenous infusion:
 - You should receive a dose of 5 mg/kg body weight, diluted in 250 ml of 5% glucose solution.
 - The dose should be administered to you over a period of 20 minutes to 2 hours.
 - Administration can be repeated 2-3 times per day.

Most side effects during treatment occur when you are administered too much of this medication.

Therefore, you should receive the lowest possible dose of this medication to minimize side effects.

See also "Have you used too much of this medication?"

Adults

- The usual dose is 5 mg for every kilogram of your weight over a period of 20 minutes to 2 hours.
- Depending on your condition, you may receive a new dose of 10 to 20 mg per kilogram of weight every 24 hours.
- In emergency situations, your doctor may decide to administer a dose of 150 mg to 300 mg in a slow 3-minute injection.
- Your doctor will monitor your response to this medication, and the dose will be adjusted accordingly.

Children and adolescents: There is limited data on efficacy and safety in children. Your doctor will decide on an appropriate dose.

Elderly: As with all patients, it is important to use the minimum effective dose. Your doctor will carefully calculate how much of this medication you should receive and closely monitor your heart rate and thyroid function.

Your doctor will switch you to amiodarone tablets as soon as possible.

Have you used too much of this medication?

Since this medication will be administered to you while you are in the hospital or under the supervision of your doctor, it is unlikely that you will be administered too much.

However, if you have received higher doses than the recommended dosage, your doctor will thoroughly monitor you and provide supportive treatment if necessary.

You may experience the following effects: nausea, vomiting, constipation, or sweating. You may have an unusually slow or fast heartbeat.

If you have any other questions about the use of this medication, please contact your doctor or other healthcare professional.

Possible side effects

Like any medication, this medication can also have side effects, although not everyone experiences them.

Amiodarone hydrochloride 50 mg/ml may still be present in your blood one month after the end of treatment. During this period, you may still experience side effects.

Stop taking amiodarone hydrochloride 50 mg/ml and contact a doctor, nurse, pharmacist, or go to a hospital immediately if:

Very rare (affects less than 1 in 10,000 users)

- You have an allergic reaction. Symptoms may include skin rash, difficulty swallowing or breathing, swollen lips, face, throat, or tongue.
- Your heart beats very slowly or stops beating.

You may also feel dizzy, more tired than usual, and short of breath. This can occur especially occur in people over the age of 65 or in people who have other problems with their heartbeat.

- Your heartbeat becomes even more irregular or unpredictable. This can lead to a heart attack, so you should go to the hospital as soon as possible.
- You develop yellow skin or yellow eyes (jaundice), feel tired or sick, have a decreased appetite, experience stomach pain, or have a fever. These could be symptoms of liver problems or liver damage, which can be very dangerous.
- You have difficulty breathing or feel pressure on your chest, persistent coughing, wheezing, weight loss, and fever. This could be due to inflammation of your lungs, which can be very dangerous.

Frequency unknown (cannot be determined from the available data)

- You have a life-threatening irregular heartbeat (Torsades de Pointes).
- You suddenly experience a swollen tongue, swollen lips, a swollen face, or a swollen throat (angioedema).
- Symptoms include skin rash and blisters. The blisters can occur in the mouth, nose, vagina, or penis. You may also experience flu-like symptoms and fever. This can be a severe illness called Stevens-Johnson syndrome.
- Severe skin rash. You may experience fever, blisters, skin peeling, and detachment of the skin. You may also feel unwell, have fever, chills, and muscle aches (Toxic Epidermal Necrolysis).
- Inflammation of the skin with fluid-filled blisters (bullous dermatitis).
- You have flu-like symptoms and a rash on your face that worsens over time, as well as blood tests showing elevated levels of a certain substance in your liver, increased levels of a specific type of white blood cells (eosinophilia), and enlarged lymph nodes (DRESS syndrome).

Stop using amiodarone hydrochloride 50 mg/ml and immediately contact a doctor if you experience any of the following side effects - you may require urgent medical assistance:

Very rare (affects less than 1 in 10,000 users)

- Headache (which is usually worse in the morning or occurs after coughing or exertion), nausea, seizures, fainting, vision problems, or confusion may occur. These could be symptoms of brain problems.

Contact your doctor as soon as possible if you experience any of the following side effects:

Common (affects less than 1 in 10 users)

- Itchy skin rash with scales (eczema).
- Dizziness, lightheadedness, or fainting. This may be temporary and caused by a drop in blood pressure.
- Frequency unknown (cannot be determined from the available data)
- Inflammation of the pancreas causing severe abdominal and back pain (pancreatitis).
- Seeing, hearing, or feeling things that are not there (hallucinations).
- You may be more prone to infections than usual. This could be caused by a decrease in the number of white blood cells (neutropenia). Severe decrease in white blood cell count leading to Increased likelihood of infections (agranulocytosis). You may become blind in one eye or have poor vision and lose the ability to see colors. Your eyes may feel painful and sensitive, and moving your eyes may cause pain. This could be a condition called "optic neuropathy" or "neuritis."
- Feeling extremely restless or excited, weight loss, increased sweating, and intolerance to heat. These could be symptoms of a condition called "hyperthyroidism."
- Excessive growth of tissue in the larger bones of the body (marrow granulomas).
- Contact your doctor, nurse, or pharmacist if any of the following side effects worsen or last longer than a few days:
- Very common (affects more than 1 in 10 users)
- Blurred vision or seeing a colored halo in flashes.
- Common (affects less than 1 in 10 users)
- Slightly slower heart rate.
- You may experience the following at the site of injection or infusion:

Pain

- Redness or change in skin color
- Local damage to soft tissue (such as the skin)
- Leakage of fluid
- Swelling due to fluid in the skin
- Inflammation or inflamed blood vessels
- Unusually hard tissue
- Infection
- Tremor when moving your arms or legs.
- Decreased libido.

Sometimes (affects less than 1 in 100 users):

- Numbness or weakness, tingling, or a burning sensation (may occur in any part of your body).

Rare (affects less than 1 in 1,000 users):

- The excipient benzyl alcohol may cause hypersensitivity reactions.

Very rare (affects less than 1 in 10,000 users):

- Changes in the levels of a certain substance in the liver (liver enzymes) at the beginning of treatment. This can be determined through blood tests.
- Nausea.
- Headache.
- Sweating.

- Hot flashes.
- Feeling unwell, confused or weak, nausea, decreased appetite, easily irritated. This could be a condition called "syndrome of inappropriate secretion of antidiuretic hormone" (SIADH).

Diseases in which your heart does not transmit electrical impulses properly (cardiac conduction disorders):

Frequency unknown (cannot be determined from available data)

- Life-threatening condition after a heart transplant where the transplanted heart does not function properly (primary graft dysfunction. See section 2, Warnings and precautions)
- Hives (skin rash with pink bumps and severe itching)
- Back pain
- Decreased libido
- Your thyroid gland is underactive (hypothyroidism) - you may experience: feeling cold, being slow, weight gain, extreme fatigue, constipation, and muscle pain.
- Confusion (delirium)

How to store this medicine:

- Your doctor or pharmacist is responsible for storing this medicine. They are also responsible for the proper disposal of the unused medicine.
- Store below 25°C. Do not refrigerate or freeze.
- Keep the ampoules in the outer packaging to protect them from light.
- Diluted solution should be used immediately.
- Keep out of sight and reach of children.
- Do not use this medicine after the expiry date stated on the label and the box after "EXP:". The expiry date refers to the last day of that month.
- Do not use this medicine if you notice that the solution is not clear and free from particles or if the packaging is damaged.
- For single-use only. Discard any unused solution.