Amiodarone Insert

Front

Amiodarone hydrochloride 100 mg tablets

Amiodarone tablets can increase your chance of getting side effects.

• You are allergic to iodine, amiodarone or any of the other ingredients of this medicine (listed in "Other ingredients"

• Iodine:
  • Lactose: these tablets contain a medicine called Amiodarone hydrochloride. This belongs to a group of medicines called

• You have a pacemaker or implantable cardioverter defibrillator (ICD). Your doctor will check that your device is working properly shortly after you start taking the tablets or if your dose is changed.

• If you have been told by your doctor that you have intolerance to some sugars, medicines or other substances (sulphites)

• If you are elderly (over 65 years of age). The doctor will need to monitor you more carefully.

• You have a pacemaker fitted

• Medicines called calcium channel blockers - for chest pain (angina) or high blood pressure (such as diltiazem, verapamil, felodipine, nifedipine or nimodipine)

• Medicines used for hepatitis C treatment (such as sofosbuvir, daclatasvir, simeprevir or ledipasvir)

• Medicines used for hay fever, rashes or other allergies called antihistamines (such as astemizole, cetirizine, loratadine, fexofenadine, antihistamines).

• Medicines for impotence such as sildenafil, tadalafil or vardenafil

• Medicines used to treat anxiety or depression (such as fluoxetine, paroxetine, clomipramine, alprazolam, citalopram, escitalopram, mirtazapine, venlafaxine, fluoxetine, paroxetine or bupropion)

• Medicines used for infections caused by certain types of bacteria or fungi (such as clarithromycin, ciprofloxacin, ofloxacin or levofloxacin)

• Medicines for inflammation (corticosteroids) such as hydrocortisone, betamethasone or prednisolone

• Medicines for treatment of high blood pressure ('calcium channel blockers') such as amiodarone, amlodipine, felodipine, nifedipine, verapamil, diltiazem, nicardipine, nisoldipine, isradipine, nicardipine, amlodipine or benidipine.

• Medicines used to treat anxiety or depression (such as fluoxetine, paroxetine, clomipramine, alprazolam, citalopram, escitalopram, mirtazapine, venlafaxine, fluoxetine, paroxetine or bupropion)

• Medicines against herpes viral infections such as famciclovir, valaciclovir or ganciclovir

• Medicines against hepatitis B treatment (such as tenofovir, entecavir or lamivudine)

• Medicines used to treat high blood pressure (such as captopril, enalapril, lisinopril, losartan, perindopril, quinapril, ramipril, telmisartan, valsartan, amlopine, moxonidine or eprosartan)

• Medicines against infections caused by certain types of bacteria or fungi (such as clarithromycin, ciprofloxacin, ofloxacin or levofloxacin)

• Medicines used to treat type 2 diabetes (such as metformin, gliclazide, sulphonylureas or insulin)

• Do not take if you are breast-feeding or plan to breast-feed. This is because small amounts of this medicine can get into your breast milk and may affect your baby. If you think you may be pregnant, or if you are not sure, tell your doctor before taking this medicine.

• You have any other problems with your heart and do not think that this tablet will help you.

• Medicines that lower your blood levels of the "good" (HDL) cholesterol (such as cholestyramine, colestipol, niacin)

• Medicines against human immunodeficiency virus (HIV) treatment (such as lamivudine, stavudine, efavirenz, nevirapine or raltegravir)

• Medicines used to treat anxiety or depression (such as fluoxetine, paroxetine, clomipramine, alprazolam, citalopram, escitalopram, mirtazapine, venlafaxine, fluoxetine, paroxetine or bupropion)

• Medicines used to treat heart failure (such as digoxin, enalapril, ramipril, quinapril, valsartan)

• Medicines that may cause your blood lipids to rise (such as corticosteroids, any of the trimethadione, phenytoin, phenobarbital, primidone, carbamazepine, sodium valproate or alcohol)
Amiodarone tablets contain:

- Each 100 mg tablet contains 100 mg of Amiodarone hydrochloride.
- Each 200 mg tablet contains 200 mg of Amiodarone hydrochloride.

The other ingredients are lactose monohydrate, maize starch, povidone, pregelatinised starch, magnesium stearate, hydroxypropyl methylcellulose, hypromellose, titanium dioxide (E171), red iron oxide (E172) and black iron oxide (E172).

Each pack contains 28 or 30 tablets. Not all pack sizes may be marketed.

How to take it

Swallow Amiodarone tablets with water or other liquid.

Missed dose

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for your next dose, you should not take a double dose to make up for the missed one. If you take more tablets than you should, see What to do if you take too much.

How to stop taking it

Keep taking Amiodarone tablets until your doctor tells you to stop. Do not stop taking Amiodarone tablets on your own. You should not stop taking Amiodarone tablets even if you feel better. If you stop taking Amiodarone tablets suddenly, you may experience heart palpitations and other symptoms of withdrawal. If you stop taking Amiodarone tablets suddenly, see What to do if you take too much.

What to do if you take too much

You should not try to vomit or give you any medicines for an overdose. If you think you may have taken too much Amiodarone tablets, contact your doctor or nearest hospital immediately. Do not take any medicines for an overdose without first checking with your doctor or pharmacist. Profile of side effects

Like all medicines, Amiodarone tablets can cause side effects.

Common

- Feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH).

Uncommon

- Burning more easily in the sun (see 'Protect your skin from sunlight' in Section 2).

Very uncommon

- Chronic liver disease (pseudo alcoholic hepatitis, cirrhosis), sometimes fatal

Other side effects

- Sensitivity to light.

Tell your doctor as soon as possible if you have any of the following side effects:

Not known (frequency cannot be estimated from the available data)

These side effects may be due to a condition called 'radiation sickness'. It is common in patients treated with radiation therapy for cancer. It can include:

- Headache, balance problems, feeling dizzy (vertigo), difficulty in getting or maintaining an erection (may affect up to 1 in 10,000 people).

- Pain, redness, swelling, infection, changes in the organ where the medicine was given or skin damage (may affect up to 1 in 100 people).

- Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH).

- Changes in the amount of liver enzymes at the beginning of treatment. This can be seen in blood tests during treatment.

- Feeling faint, dizzy, unusually tired and short of breath. These could be signs of an illness called 'myasthenia gravis'.

- Feeling tired, faint, dizzy or having pale skin. These could be signs of anaemia.

- Headache, balance problems, feeling dizzy (vertigo), difficulty in getting or maintaining an erection (may affect up to 1 in 10 people).

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